AUC in Lumbar Degenerative Scoliosis

Kamal Ibrahim, MD, FRCS(C), MA
President-Elect, SRS

This talk is the courtesy of Steve Glassman, MD
Vice President- SRS

AUC in Lumbar Scoliosis

Why?

- Continuous challenge of the Indications for any Spine Fusion other than Spondylolisthesis
- Persistent conflicts with payers, government agents, even hospitals

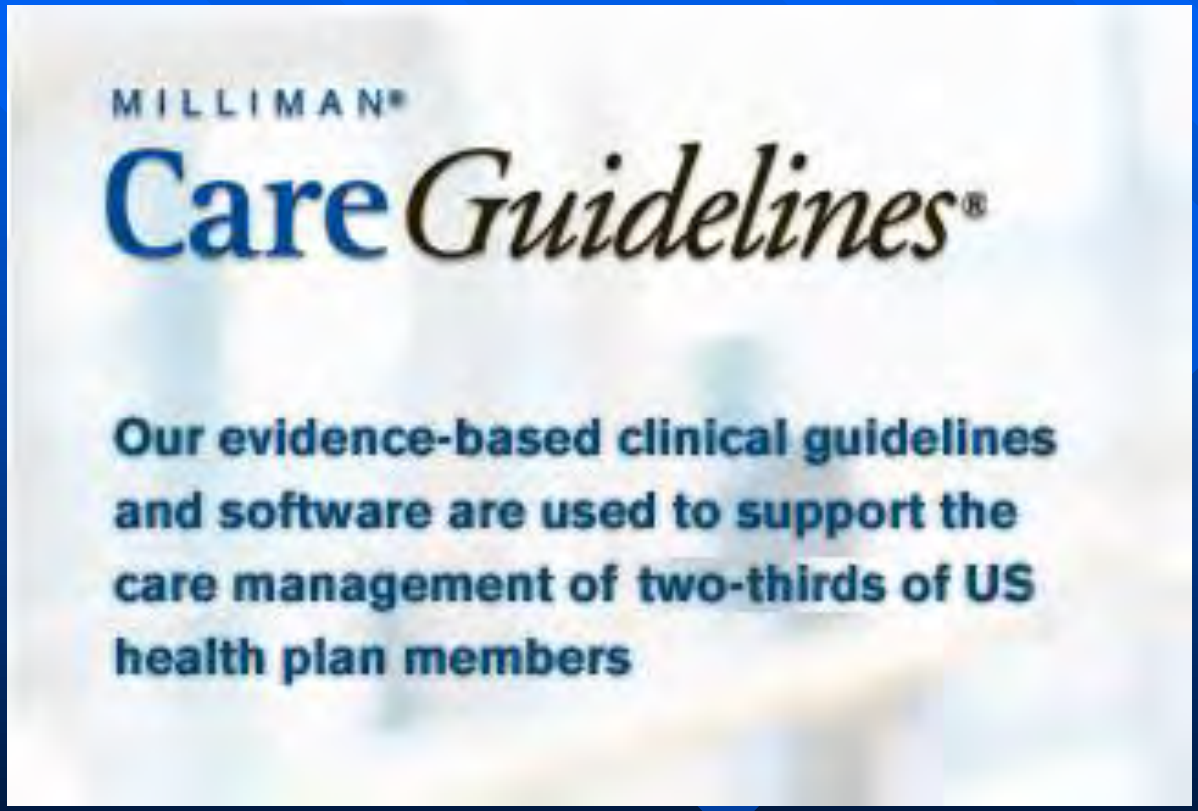
CMS, Proposed NCD Topics -2008

Lumbar fusion for degenerative disc disease: For certain patients, a two level spinal fusion may be an effective treatment for debilitating back pain from two degenerated lumbar discs. Multilevel fusion as a primary treatment for low back pain *from degenerated discs is a controversial topic in spine medicine.*

*However, **lumbar fusion of three or more** levels of the low back as a primary treatment for back pain is rarely recommended, and many surgeons recommend against it in all cases of multilevel degenerative disc disease.*

Is the evidence adequate to specify who will and who will not benefit from the lumbar fusion procedure?

Nontransparent, For-Profit Guidelines



BlueCross BlueShield of North Carolina

An independent licensee of the Blue Cross and Blue Shield Association

Corporate Medical Policy

Lumbar Spine Fusion Surgery "Notification"

File Name:	Lumbar_spine_fusion_surgery
Origination:	9/2010
Last CAP Review:	N/A
Next CAP Review:	5/2011
Last Review:	9/2010

BC/BS North Carolina Proposed Fusion Guidelines September 2011

When Lumbar Spine Fusion Surgery is covered

BCBSNC will provide coverage for Lumbar Spinal Fusion procedures for any one of the following conditions:

1. Spinal Fracture with instability or neural compression
2. Spinal repair surgery for dislocation, abscess or tumor
3. Spinal Tuberculosis
4. Spinal Stenosis with ALL of the following:
   a. Associated spondylolisthesis demonstrated on plain x-rays; and
   b. Any one of the following:
      - Neurogenic claudication or radicular pain that results in significant functional impairment in a patient who has failed at least 3 months of conservative care and has documentation of central/lateral recess/or foraminal stenosis on MRI or other imaging. or
      - Severe or rapidly progressive symptoms of neurogenic claudication or cauda equina syndrome.

Lumbar Fusion for Spondylolisthesis

The Solution is to conduct studies to validate appropriate surgical management

Sustainable Strategies

- **Long term**
  - **Generate high quality prospective data (Registries)**
- **Short/Medium term, (needed now)**

Short Term Strategies

- **Appropriate Use Criteria (AUC)**
  SRS
- **Clinical Guidelines** - NASS/CNS
- **Medical Modeling** - Covance

Why Degenerative Lumbar Scoliosis

- ✓ Primary interest for SRS
- ✓ Reasonable literature base
- ✓ Recognition that the procedure is indicated, but target population not adequately defined

AUC in Lumbar Scoliosis

SRS and AANS agreed to proceed with AUC, RAND Institute was chosen

- **Face Validity**
- **Firewall for bias concerns**
- **Payer Acceptance**

AUC in Lumbar Scoliosis

Advantages to RAND AUC Project

- **Alter the assumption that:**

"Spondylolisthesis is the only appropriate indication for fusion"

AUC in Lumbar Scoliosis

The project of AUC with RAND

- Price Tag - $580,000
- should be completed in 18 months
- completely independent of SRS/AANS

Choosing Wisely

An Initiative of the American Board of Internal Medicine Foundation

F. Todd Wetzel MD

Director, Administration and Development

Board of Directors, North American Spine Society

Spine Summit, August, 2012

ChoosingWisely

- SIG Meeting, NASS, February 2012
- ABIM initiative
- Discussed on a Health Policy conference call
- Discussed with Daniel Wolfson, Dr. Jerome Schofferman, Laura Sawyer
- Discussion with Daniel Wolfson, Tim Lynch

ChoosingWisely

- “Five Things Physicians and Patients Should Question”
- Background
  - Physician-patient partnership
  - 30% care delivered in US “unnecessary” (CBO)
  - 2019- health care spending will be 19.3% of GDP
- The Campaign
- Partners to date

ChoosingWisely

- “Five Things Physicians and Patients Should Question”
- Background
- The Campaign
  - ABIM
  - Consumer Reports
  - Identify 5 procedures/tests whose use should be discussed or questioned; develop tools for dialogue
- Partners to date

ChoosingWisely

- “Five Things Physicians and Patients Should Question”
- Background
- The Campaign
- Partners to date
  - 9 non surgical specialty societies
  - 2 surgical societies
  - Roughly 400,000 physicians in all societies
  - *Consumer Reports*

ChoosingWisely

- How Would this work?
  - 3.15.12: deadline for yea/nay for 2nd Phase
  - 4.4.12: announcement of 1st Phase partners and lists
  - 9.1.12: deadline for 5 things
    - “turnkey communication”
  - 9.12: Consumer Union to “translate” 5 things
    - Staff at Consumer Reports, including one physician
  - 10.12: 2nd Phase announcement
  - That said, the initiative is quite flexible. TBD at NASS annual meeting, 2012

ChoosingWisely

- Press conference, National Press Club, April 2012
  - 9 Society Presidents, President of ABIM Foundation (Dr Christine Cassel) and President of *Consumer Reports* (Jim Guest)
  - Guest: 34% of patients request unnecessary testing; 66% of physicians oblige
  - Well received
  - Emphasized that this is not about “never ordering a test”
  - Patient as a partner
  - Animated, positive discussion from the press

ChoosingWisely

- Pros
  - Leadership
  - Self criticism/ self awareness
  - Perception as patient advocacy
  - Excellent PR
  - Tone has changed: far less strident than initially

ChoosingWisely

- Cons:
  - Lack of overall control
  - Additional time and administrative burden to office staff that is already stretched
  - Given the current political, legal and regulatory environment, are we “stirring the pot”?
  - Misuse- legal implications
    - ABIM disclaimer (protects only ABIM)
  - Misuse as guidelines or regulatory lists
    - Foundation position is that efforts such as this represent the best way to get the government NOT to regulate

ChoosingWisely

- Other Factors
  - ABOS elected not to participate
  - Potentially negative reaction of the membership
  - What is missing
    - *NO mention of the role of medicolegal issues in driving up costs*
    - *NO mention of tort reform*

ChoosingWisely

- Clearly a Hot Button issue
  - If this is, philosophically, a good idea, can the potential down sides or misuses be controlled and managed to keep the good information at the forefront?

  - Membership involvement
    - Devil is in the details
    - General referendum unwieldy
    - Program at Annual Meeting?
    - Solicit the membership for a list of 5; EBM review; membership vote?

ChoosingWisely

- Next Steps
- Board meetings
- Contact with ABIM Foundations principals
- Presentation to various society memberships
- All in or all out?

CURRENT REIMBURSEMENT ISSUES

Spine Summit

August 10, 2012

Gregory J. Przybylski, M.D.

NJ Neuroscience Institute at JFK

Seton Hall University

DISCLOSURES

United Healthcare: Spine Advisory Board
Magellan Health: Consultant
Eli Research: Editorial Consultant, Speaker

NASS: Immediate Past President
AMA: Relative-value Update Committee AANS Representative
CMS: Ambulatory Payment Classification Panel

CPT Editorial Panel

- AMA Committee
- Appointment by AMA Board of Trustees
- Membership limited
- Proposed revision of criteria for Category I code
  - No longer “require” specialty society support
  - May marginalize the role of physician advisors
  - Category I status no longer implies coverage

Relative-value Update Committee

- AMA Committee
- 27 voting members (formerly 25)
- Membership criteria previously limited members
- Primary care has 2 additional members (geriatric, other)
- Value new and revised CPT codes
  - 2/3 vote to pass a value (balance has changed)
  - Primary care vs surgical vs “procedural”
  - Submits recommendations to CMS

Relative-value Update Committee

- MedPac Pressure
  - Procedures increasing in value over time
  - Primary care shortage:2º low compensation
- AMA Pressure
  - Political organization responding to government
  - CPT monopoly as financial driver

RUC 5 YR ID WORKGROUP

- Response to MedPAC Criticism of RUC
- Screens for potentially mis-valued codes
- A priori assumption of overvaluation (vs mis-valued)
- Responds to CMS requests
- Initiates screens
- Significant risk for reduction in values

CMS IDENTIFICATION: INITIAL CRITERIA

- Fast-growing procedures

  >10%/yr for 3 yrs

  >$1 million charges annually
- Concurrent procedures (component coding)

  Done together >90% of the time (eg ACDF)
- Harvard study valued procedures

CMS IDENTIFICATION: EXPANDING CRITERIA

- Low RVU with multiple units reported
- Low RVU with high volume
- 23 hour stay/Site of service changes
- Concurrent procedures (component coding) done together >75% of the time (eg PLIF/PLF, ACDF)
- MPC Codes (eg LP, Discectomy, Laminectomy Laminoplasty, Carpal Tunnel, Lumbar Plexus Infusion)

23 HOUR STAY

- Inpatient procedures classified by hospital as outpatient
  - RUC valued these codes various ways
  - No E&M service surrogate
  - CMS proposed reduction in discharge value, reduce value by inpatient visits, bundle in time (reduces intensity)
- Basis for reduction is formulaic removal of inpt E&M
- Inpatient procedure routinely done as outpatient (63030, 22551)

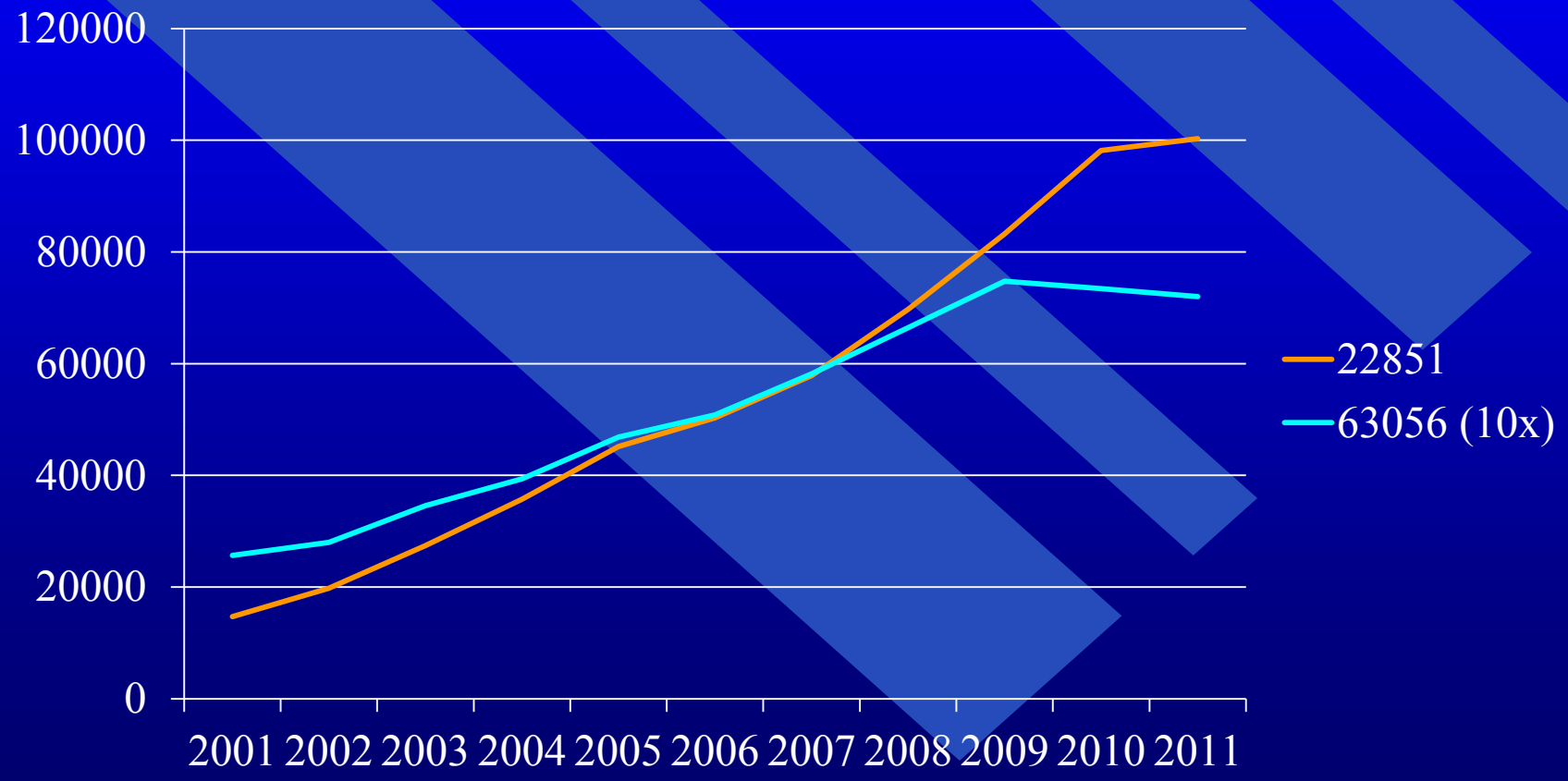
RECOMMENDATION: Maintain unanimity among our societies regarding the value of procedures using comparison values and intensities. The work performed must be acknowledged and accounted for.

FUTURE PROCEDURES: The Unforeseen Threat

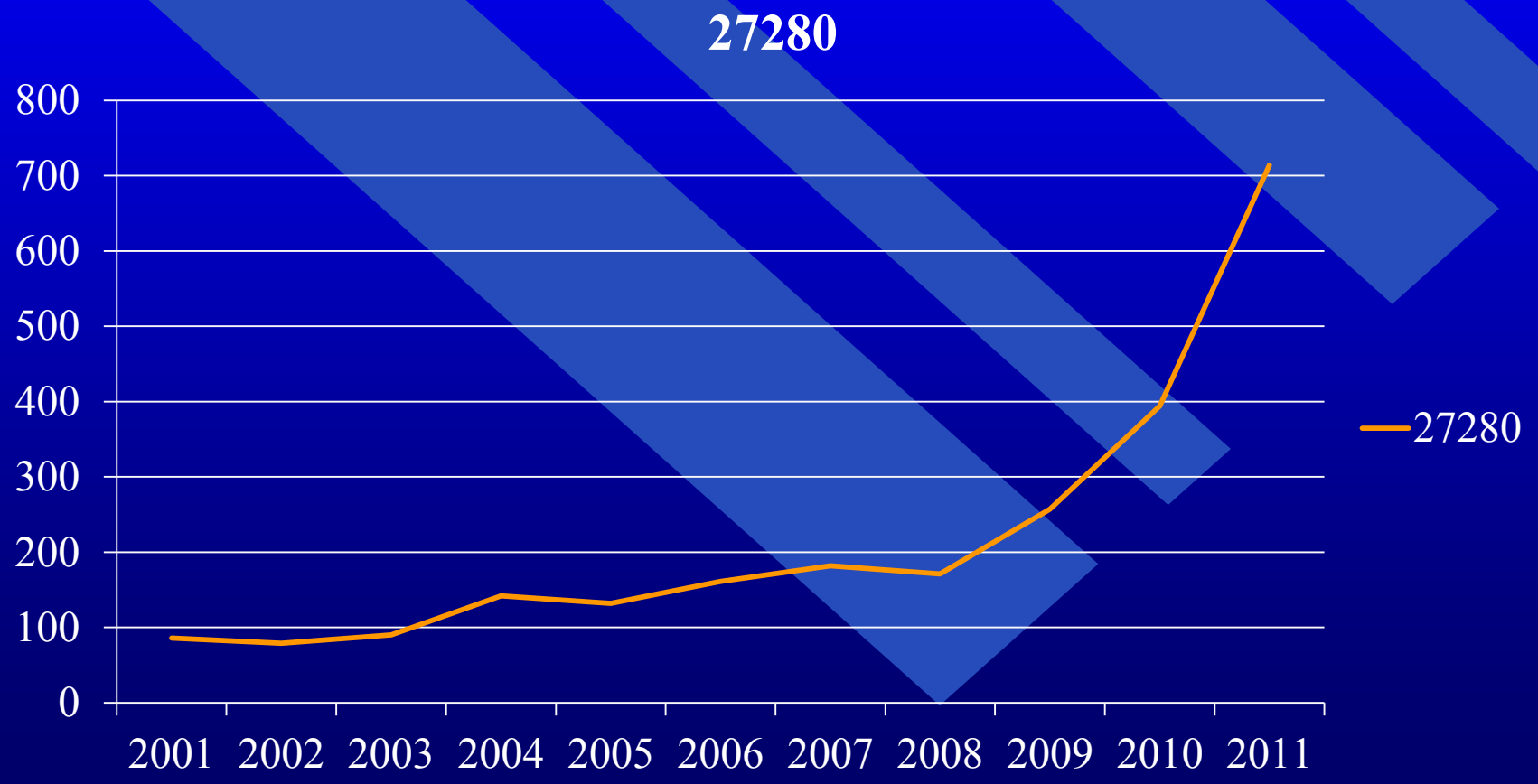
- Rapidly growing services (eg 22851, 63056, 27280)
  - New technologies are being described w existing codes
  - Leads to unexpected growth in service volumes
  - Leads to identification on 5 YR ID screens

RECOMMENDATION: Educate members about correct coding and develop appropriate level codes preemptively to prevent miscoding.

11 YEAR MEDICARE GROWTH: ALREADY IDENTIFIED BY RUC



11 YEAR MEDICARE GROWTH: RISK OF IDENTIFICATION BY RUC



FUTURE PROCEDURES: The Unforeseen Threat

- Bundled payments
  - –CMS demonstration projects in hip arthroplasty, CABG
  - –3rd Party Payers exploring bundled payments
  - –High volume spinal procedures likely to be considered

RECOMMENDATION: Consider developing alternative methods to measure the value of high/growing volume & expensive spinal procedures.

FUTURE PROCEDURES: The Foreseen Threat

- Independent Payment Advisory Board
  - 15 member appointed panel
  - Charged with reducing CMS expenditures
  - Oversight if not replacement of RUC influence

RECOMMENDATION: Encourage membership to contact Congressional representatives to support IPAB repeal.

3rd PARTY PAYERS: EXPANDING NON-COVERAGE

- New technology critically reviewed (tech assessments)
- Previously approved procedures being reviewed (fusion)
- Approval often based on Milliman criteria

RECOMMENDATION: Encourage society representative to work with 3rd party payers in review of proposed coverage criteria. Consider prospective development of coverage criteria.

Third Party Payer Coverage Policies

AANS/CNS Committee For Payer and Policy Responses

Joseph S. Cheng, M.D., M.S.

Chairperson

AANS/CNS SECTION ON DISORDERS OF THE SPINE AND PERIPHERAL NERVES

AANS/CNS Committee For Payer and Policy Responses

- **Mission:** To promote access to beneficial surgical care for patients with neurosurgical disorders affected by payers and health care policies through evidence based research, education, and proven outcomes.

- **Vision:** To provide our patients with access to the highest quality neurosurgical care.

2012 Regional Structure

- Director – Joseph Cheng
- Associate Director – Charley Sansur
- Quadrant Directors
  - Northeast – Peter Angevine
  - Southeast – Karin Swartz
  - Northwest – John Ratliff
  - Southwest – Lou Tumialan

Regulatory Affairs Manager

- Cathy Hill, Senior Manager, Regulatory Affairs
  - Point person to coordinate responses
  - Manages payor policy responses, CPT, and RUC
  - Coordinates volunteer physicians
  - Maintains database of all insurance policies that relate to neurosurgery
  - Maintains database of all AANS/CNS responses to insurance policies

2011-2012 Third Party Payer Coverage Issues

AANS/CNS Member Issues

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS
THOMAS A. MARSHALL, *Executive Director*
5550 Meadowbrook Drive
Rolling Meadows, IL 60008
Phone: 888-566-AANS
Fax: 847-378-0600
info@aans.org

President
PAUL C. MCCORMICK, MD, MPH
New York, New York

American Association of Neurological Surgeons

CONGRESS OF
NEUROLOGICAL SURGEONS
REGINA SHUPAK, *Acting Executive Director*
10 North Martingale Road, Suite 190
Schaumburg, IL 60173
Phone: 877-517-1CNS
FAX: 847-240-0804
info@1CNS.org

President
CHRISTOPHER E. WOLFLA, MD
Milwaukee, Wisconsin

February 10, 2012

Jeffrey R. Schell, Esq.
Of Counsel, Michigan Clinic
4200 Fashion Square Boulevard
Suite 300
Saginaw, Michigan 48603

RE: **Minimally Invasive Lumbar Fusions**

Dear Mr. Schell:

The Coding and Reimbursement Committee of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) appreciates the opportunity to review and comment on the issue of minimally invasive lumbar fusions.

The information you provided regarding a Blue Cross Blue Shield of Michigan Audit, specifically a letter from Rhonda Thomas, Manager Utilization Review dated June 14, 2011 stating that "it is felt that mini-invasive lumbar spine fusions by any method is investigational". You noted that "according to our physicians, though the procedures utilized some minimally invasive techniques, they were standard, open lumbar fusions". After careful review of the provided documents, we offer the following comments.

To clarify, American Medical Association (AMA) CPT codes are developed to best describe a surgical technique not a specific device and/or instrument. When the instrument is used in any fashion without direct visualization of the neurologic structures by naked eye/microscope and or loupe magnification then it would be consistent with a percutaneous procedure.

- CPT code 22899 Unlisted procedure, spine – for percutaneous spinal interbody fusions performed without direct visualization of the neurological structures.
- CPT Category III code 0221T Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar

Anthem

Anthem

Medical Policy

Subject: Artificial Intervertebral Discs
Policy #: SURG.00055
Status: Revised
Current Effective Date: 10/12/2011
Last Review Date: 08/18/2011

Description/Scope

This document describes the use of lumbar and cervical artificial intervertebral discs to treat degenerative disc disease (DDD) of the spine.

Position Statement

Investigational and Not Medically Necessary:

Lumbar artificial intervertebral discs are considered **investigational and not medically necessary.**

Cervical artificial intervertebral discs are considered **investigational and not medically necessary.**

Anthem

Anthem
Health. Join In.

CUSTOMIZATIONS TO MILLIMAN CARE GUIDELINES®
14th EDITION

Issue Date:	Original Date:
March 3, 2011	March 9, 2010

NOTE:

- *This document provides a high level summary of customizations and modifications made to Milliman Care Guidelines® (hereinafter referred to as "Customized Guidelines").*
- *Customized Guidelines are available on request.*
- *Benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in the Customized Guidelines. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, as well as applicable state and/or federal law. The Customized Guidelines do not constitute plan authorization or a guarantee of payment, nor are they an explanation of benefits.*
- *We reserve the right to review and modify the Milliman Care Guidelines or Customized*

Aetna

American Association of Neurological Surgeons

AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

AOSPINE NORTH AMERICA

SAS

NASS

Scoliosis Research Society Founded 1966

March 8, 2011

Lonny Reisman, MD
Aetna Chief Medical/Clinical Officer
151 Farmington Avenue
Hartford, CT 06156
860-273-0970

Subject: Clinical Policy Bulletin: Spinal Surgery: Laminectomy and Fusion Number: 0743

AHRQ

Scientific Resource Center, Oregon EPC
Mail code: BICC
3181 S.W. Sam Jackson Park Road
Portland, Oregon 97239-3098

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), we would like to thank the Agency for Healthcare Research and Quality (AHRQ) for the opportunity to comment on the key questions regarding proposed research on the topic of "***Spinal Fusion for Painful Lumbar Degenerative Disc or Joint Disease***". We have appreciated the efforts of AHRQ's Effective Health Care Program, and the research summaries regarding the benefits and risks of different treatment options of health conditions based on comparative effectiveness reviews. We also understand that these research summaries are not clinical recommendations or guidelines, but are nevertheless frequently utilized as such with respect to healthcare policy development.

For the formulation of each of these Key Questions (KQs), AHRQ has requested a description of the included studies including patient indications, methods of diagnosis, inclusion and exclusion criteria, treatments, and surgical techniques and devices used. The AANS/CNS, along with other medical societies, have developed clinical guidelines on this topic and do not feel that another systematic review of these questions will yield useful information where our previous efforts have concluded that there is a paucity of sufficient data and that the quality of the studies is limited. However, as evidenced by the similar limitations in other medical and surgical topics, this does not diminish the benefit of this surgical treatment to our patients. Questions posed for the "Comment on Key Questions" may not be clinically

BCBS-MA

MASSACHUSETTS

January 13, 2011

Dear Health Care Leader,

As 2011 begins, I want to thank each of you for the care that you and your organizations give to our members who are your patients. Every day, we hear about the skill and commitment of caregivers in Massachusetts, and about how much it means to our members and their health.

At the same time, we all know that rising costs continue to threaten the health care that is so important to our community. Health care costs are making businesses in Massachusetts less competitive, and limiting their ability to grow. Health care costs are squeezing municipal budgets, taking money from schools and police and fire protection, and health care costs are consuming too much of family incomes, forcing many families to make difficult sacrifices.

For BCBSMA, making quality health care affordable is our highest priority. The two components that drive our premiums are administrative cost and the cost of medical care. We have worked aggressively to lower our

BCBS-TN

BlueCross BlueShield of Tennessee Medical Policy Manual

Artificial Intervertebral Disc

DESCRIPTION

A variety of artificial intervertebral discs are being investigated as an alternative to spinal fusion. This approach, also referred to as total disc replacement or spinal arthroplasty, is intended to maintain motion at the operative level once the damaged disc has been removed, and to maintain the normal biomechanics of the adjacent vertebrae. The devices (e.g., BRYAN™, CHARITE™, MAVERICK™, PRESTIGE®, ProDisc™-C, PRODISC®-L) use 2 metal endplates that are press fit into adjacent vertebrae and a central free component. This central component is held into place by the surrounding normal soft tissues (such as ligaments and the disc annulus), and shifts dynamically within the disc space during spinal motion. These devices are designed to restore disc height and normal physiologic motion. This medical policy is intended to address the use of artificial intervertebral disc at all levels of the spine (i.e., cervical, thoracic, lumbar).

POLICY

- Artificial intervertebral discs are considered ***investigational.***

BCBS-NC

DECEMBER 22, 2010, 4:44 P.M. ET

Medical Groups Take Issue With Insurers' Spine Surgery Rule

Article

By Jon Kamp
Of DOW JONES NEWSWIRES

A collection of nine medical associations is arguing against new restrictions on spinal-fusion surgery set by a health insurer in North Carolina amid concerns such restrictions could limit patient care and spread to other states.

Whether the groups can alter the new rules from Blue Cross and Blue Shield of North Carolina, which go into effect Jan. 1, remains to be seen. But the response is evidence doctors are joining forces to battle ongoing insurance pressure on the spinal-fusion market. Several spinal device-makers, most recently NuVasive Inc. (NUVA), have cited signs insurers are raising barriers to such procedures amid concerns they're over-utilized.

Doctors worry the new policy in North Carolina, which is seen as particularly restrictive, could further dampen an already slowed market if it spreads elsewhere.

"We certainly see that once even a local area starts coming up with these policies, others may start adopting it," said Joseph Cheng, who directs the neurosurgery spine program at Vanderbilt University Medical Center in Nashville, Tenn. He also serves on the coding and reimbursement team for the American Association of Neurological Surgeons, which co-signed the letter.

The letter was sent last week and also signed by the American Association of Orthopaedic Surgeons, the Scoliosis Research Society and the North American Spine Society, among other groups. They said they "have concerns regarding the criteria and guidelines" in the new coverage policy, and they proposed less restrictive language.

BCBS-NC

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS
THOMAS A. MARSHALL, *Executive Director*
5550 Meadowbrook Drive
Rolling Meadows, IL 60008
Phone: 888-566-AANS
Fax: 847-378-0600
info@aans.org

President
PAUL C. MCCORMICK, MD, MPH
New York, New York

American Association of Neurological Surgeons

CONGRESS OF
NEUROLOGICAL SURGEONS
LAURIE BEHNCKE, *Executive Director*
10 North Martingale Road, Suite 190
Schaumburg, IL 60173
Phone: 877-517-1CNS
FAX: 847-240-0804
info@1CNS.org

President
CHRISTOPHER C. GETCH, MD
Chicago, Illinois

June 9, 2011

Don W. Bradley, MD
Chief Medical/Clinical Officer
Blue Cross and Blue Shield of North Carolina (BCBSNC)
5901 Chapel Hill Road
Durham, NC 27707

Subject: BlueCross BlueShield of North Carolina Lumbar Laminectomy, Facetectomy or Foraminotomy reported with a Lumbar Spinal Fusion Bundling Guidelines "Notification"

Dear Dr. Bradley:

BCBS-TN

of Tennessee

TRIAD HEALTHCARE
MUSCULOSKELETAL HEALTH SERVICES

IMPROVING QUALITY THROUGH THE DELIVERY OF EFFECTIVE AND EFFICIENT MUSCULOSKELETAL CARE

Provider Orientation
developed by Triad Healthcare

Physical Medicine
Pain Management
Spine and Joint Surgery

1

Cigna

CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Intervertebral Disc (IVD) Prostheses**

Effective Date **12/15/2009**
Next Review Date **12/15/2010**
Coverage Policy Number **0104**

Table of Contents

Hyperlink to Related Coverage Policies

Bone Graft Substitutes for Use in Bone Repair
Bone Growth Stimulators: Electrical (Invasive, Noninvasive), Ultrasound
Intradiscal Electrothermal Annuloplasty
Lumbar Fusion for Spinal Instability and Degenerative Disc Conditions
Minimally Invasive Treatment of Back Pain
Spinal Orthoses

Cigna

CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all plans administered by CIGNA Companies including plans administered by Great-West Healthcare, which is now a part of CIGNA.

Subject **Lumbar Fusion for Spinal Instability and Degenerative Disc Conditions**

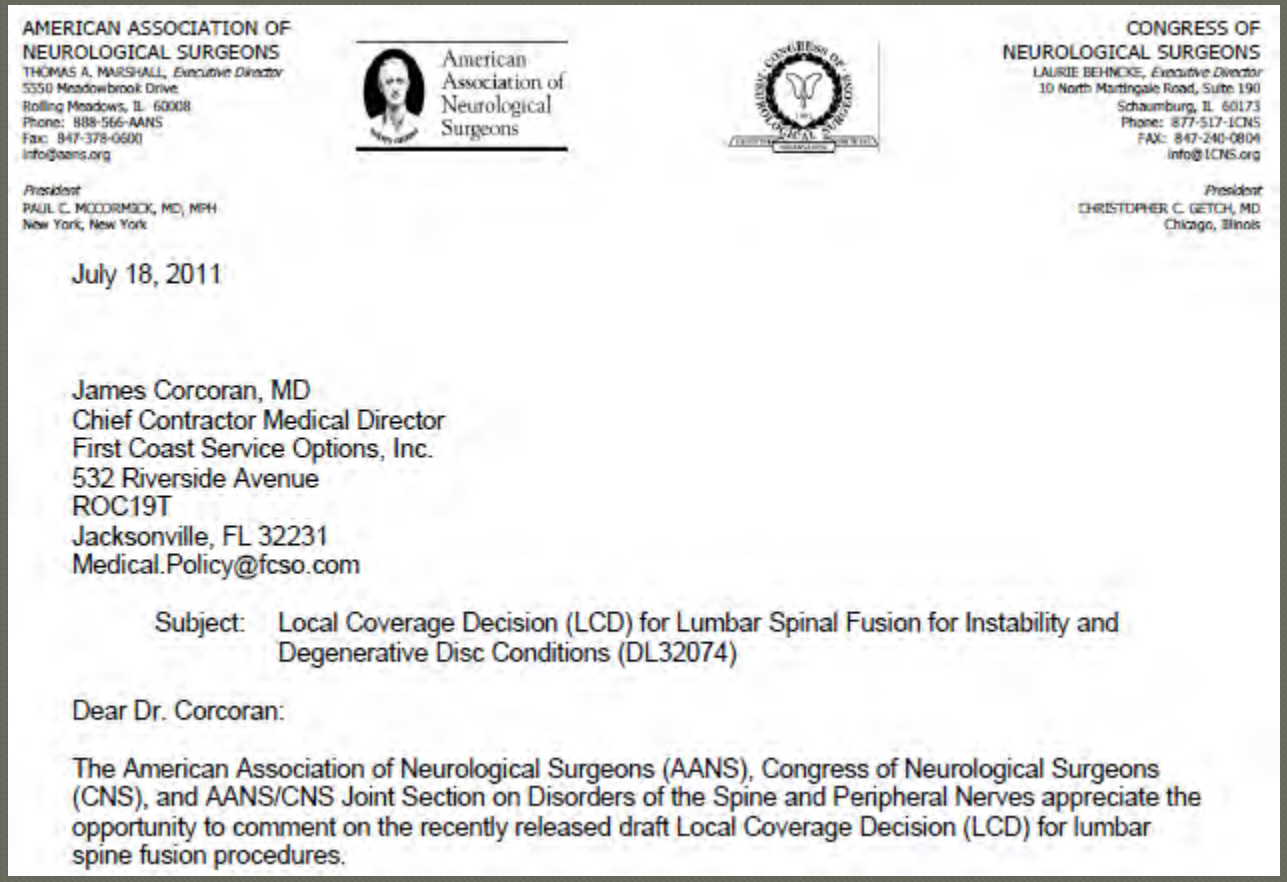
Effective Date 12/15/2009
Next Review Date 12/15/2010
Coverage Policy Number 0303

Table of Contents

Hyperlink to Related Coverage Policies

Bone Graft Substitutes for Use in Bone Repair
Bone Growth Stimulators: Electrical (Invasive, Noninvasive), Ultrasound
Discography
Intervertebral Disc (IVD) Prostheses
Intradiscal Electrothermal Annuloplasty
Minimally Invasive Treatment of Back Pain
Percutaneous Vertebroplasty and Kyphoplasty

CMS LCD-FL



AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS
THOMAS A. MARSHALL, *Executive Director*
5550 Meadowbrook Drive
Rolling Meadows, IL 60008
Phone: 888-566-AANS
Fax: 847-378-0600
info@aans.org

President
PAUL C. MCCORMICK, MD, MPH
New York, New York

American Association of Neurological Surgeons

CONGRESS OF
NEUROLOGICAL SURGEONS
LAURIE BEHNCKE, *Executive Director*
10 North Martingale Road, Suite 190
Schaumburg, IL 60173
Phone: 877-517-1CNS
FAX: 847-240-0804
info@1CNS.org

President
CHRISTOPHER C. GETCH, MD
Chicago, Illinois

July 18, 2011

James Corcoran, MD
Chief Contractor Medical Director
First Coast Service Options, Inc.
532 Riverside Avenue
ROC19T
Jacksonville, FL 32231
Medical.Policy@fcso.com

Subject: Local Coverage Decision (LCD) for Lumbar Spinal Fusion for Instability and Degenerative Disc Conditions (DL32074)

Dear Dr. Corcoran:

The American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), and AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves appreciate the opportunity to comment on the recently released draft Local Coverage Decision (LCD) for lumbar spine fusion procedures.

CMS LCD-NGS (CT/NY)

MEDICAL POLICY DRAFT TO REVIEW

SUBJECT: MINIMALLY INVASIVE/MINIMAL ACCESS TECHNIQUES FOR LUMBAR INTERBODY FUSION ~~(AXIAL LUMBAR INTERBODY FUSION/AxiaLIF AND EXTREME LATERAL INTERBODY FUSION/XLIF)~~	EFFECTIVE DATE: 08/20/09 REVISED DATE: 08/19/10
POLICY NUMBER: 7.01.83	
CATEGORY: Technology Assessment	PAGE: 1 OF: 9

- *If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.*
- *Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.*
- *Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.*

POLICY STATEMENT:

I. Based upon our review and assessment of peer-reviewed literature, the following minimally invasive/minimal access techniques for interbody lumbar fusion have been medically proven to be effective and therefore can be considered as a treatment option to open standard lumbar fusion:
   - A. Anterior Lumbar antibody fusion (ALIF);
   - B. Posterior lumbar antibody fusion (PLIF); or
   - C. Transforaminal lumbar antibody fusion (TLIF).

II. Based upon our criteria and assessment of peer-reviewed literature, the following minimally invasive/minimal access techniques for interbody lumbar fusion have not been medically proven to be effective and are considered **investigational** either as a stand-alone procedure or as an adjunct to standard spinal fusion:
   - A. Extreme lateral interbody fusion (XLIF®);
   - B. Direct lateral interbody fusion (DLIF);
   - C. Axial lumbar interbody fusion (AxiaLIF®); or
   - D. Laparoscopic anterior lumbar interbody fusion (LALIF).

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

CMS NCCI

National Correct Coding Initiative
Correct Coding Solutions, LLC
A Medicare Contractor
P.O. Box 907
Carmel, IN 46082-0907
Fax: 317-571-1745

February 1, 2011

Joseph Cheng, MD
American Association of Neurological Surgeons / Congress of Neurological Surgeons
725 Fifteenth Street, NW, Suite 800
Washington, DC 20005

Dear Dr. Cheng:

I thank you for your email dated January 28, 2011 in which you inquire about the National Correct Coding Initiative (NCCI). We discussed your email with CMS (Centers for Medicare and Medicaid Services) which owns NCCI and makes all decisions about its contents.

You request that the NCCI edits with column one/column two CPT codes, 61781-61783/69990 be modified to allow use of NCCI-associated modifiers. These edits were implemented January 1, 2011 not allowing use of NCCI-associated modifiers.

CMS will modify the edits to allow use of NCCI-associated modifiers. These edits are based on the CMS *Internet Only Manual (IOM), Medicare Claims Processing Manual*, Chapter 12, Section 20.4.5 (Allowable Adjustments) which limits the separate reporting of use of the operating microscope (CPT code 69990) to certain procedures. (See copy of IOM section

CMS Noridian

January 10, 2012

Bernice Hecker MD, MHA, FACC
Medicare Contractor Medical Director, Parts A&B
Noridian Administrative Services
AK, ID, MN, OR, WA & J3 States (AZ, MT, ND, SD, UT, WY)

Dr. Hecker:

The American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), and AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves appreciate the opportunity to comment on the Noridian Local Coverage Decision (LCD) which is "under consideration" for Lumbar Spine Fusion procedures.

Organized neurosurgery agrees with the general tenets of conservative treatment for low back pain (LBP). LBP is, for the majority of patients, a self-limited phenomenon that does not require radiographic evaluation or operative intervention. We also agree with recommendations that non-operative treatments be completed prior to consideration of operative therapy. We believe that the surgeon's clinical judgment and the individual patient's needs should take precedence over strict and rigid time frames for non-operative therapy.

The AANS and CNS hope that any guidelines considered for the Noridian Lumbar Fusion LCD will

CMS Noridian

June 9, 2011

William Mangold, M.D., J.D.
George Waldmann, M.D.
Noridian Administrative Services, LLC
900 42nd Street S
P.O. Box 6740
Fargo, ND 58108

Re: Draft LCD DL24383: Vertebroplasty, Vertebral Augmentation; Percutaneous

Dear Dr. Mangold and Dr. Waldmann:

The American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves would like to thank both of you and Noridian Administrative Services, LLC for the opportunity to provide comment on the recently proposed draft policy from Noridian to change the current local coverage determination (LCD) for vertebral augmentation for osteoporotic compression fractures. While we applaud the goal of improving patient care through application of scientifically grounded therapies, we have concerns regarding the criteria set forth by Noridian for coverage of percutaneous vertebroplasty and vertebral augmentation. Below we review our concerns with various restrictions and criteria set forth for coverage.

1. Metatstatic disease: We would first like to address perhaps the most important issue and that is coverage for those individuals who may have widely metastatic disease and

Empire BCBS

Empire BlueCross BlueShield

Medical Policy

Subject: Cervical and Thoracic Discography
Policy #: RAD.00053
Status: Reviewed

Current Effective Date: 04/13/2011
Last Review Date: 02/17/2011

Description/Scope

Discography, also known as provocative discography, has been used in the diagnosis of cervical and, to a limited extent, thoracic pain syndromes in individuals being considered for surgical intervention. The contemporary use of discography involves a pressure-monitored injection of one to three (1-3) ml of contrast agent through a fine needle introduced into the center (nucleus pulposus) of an intervertebral disc followed by CT imaging to evaluate the nature and extent of suspected abnormal vertebral disc morphology. The rationale is that if a disc is symptomatic, stressing that disc will reproduce the individual's pain while stressing adjacent discs will not. The objective is to characterize the pain response (if any) on disc injection and observe whether discographic pain is concordant, i.e. able to reproduce the individual's pain syndrome.

Humana

April 4, 2011

Steven Goldberg, M.D.
Medical Director for Clinical Policy
Humana, Inc.
The Humana Main Street Bldg 500
Louisville, KY 40202

Subject: Medical Coverage Policy on Computer Assisted Surgical Navigation, Policy Number CPD-0489-003 (Revised Date: 01/01/2011)

Dr. Goldberg,

The American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves would like to thank the you and Humana, Inc. for the opportunity to provide comment on your medical coverage policy on Computer Assisted Surgical Navigation (CASN) (Policy Number: CPD-0489-003) which was revised on January 1, 2011. We applaud the goal of improving patient care through application of scientifically grounded therapies as reflected in your coverage decision that computer assisted surgical navigation using Food and Drug Administration (FDA) approved systems may be eligible for coverage, such as for "aiding precise localization of anatomical structures in either open or percutaneous procedures".

Medicaid-NC

Division of Medical Assistance
Spinal Surgery

Clinical Coverage Policy No.: 1A-30
Original Effective Date: January 1, 1974
Revised Date:

DRAFT

3. Spinal infection confirmed by imaging studies (e.g., CT or MRI) and/or other studies (e.g., biopsy), which may be combined with a laminectomy;
4. Spinal tumor confirmed by imaging studies (e.g., CT or MRI), which may be combined with a laminectomy;
5. Spondylolisthesis with segmental instability confirmed by imaging studies (e.g., CT or MRI), when both of the following criteria are met:
   A. Spondylolisthesis, Grade II, III, IV, or V (Refer to **Subsection 1.1** definitions) and
   B. Symptomatic unremitting pain that has failed six months of conservative management; or

~~6.~~Spinal stenosis with unremitting pain confirmed by imaging studies (e.g., CT or MRI demonstrating lateral recess and central stenosis at the level in question. Foraminal stenosis should involve compression on the exiting nerve root if this is being used as the 'stenosis' part of the surgical indication) that has failed three months of conservative management when *any* of the following is met:

6.
   A. Decompression is performed in an area of segmental instability as manifested by gross movement on flexion-extension radiographs of 4mm or greater;

Comment [M9]: Isthmic, congenital, post-traumatic Spondylolysis

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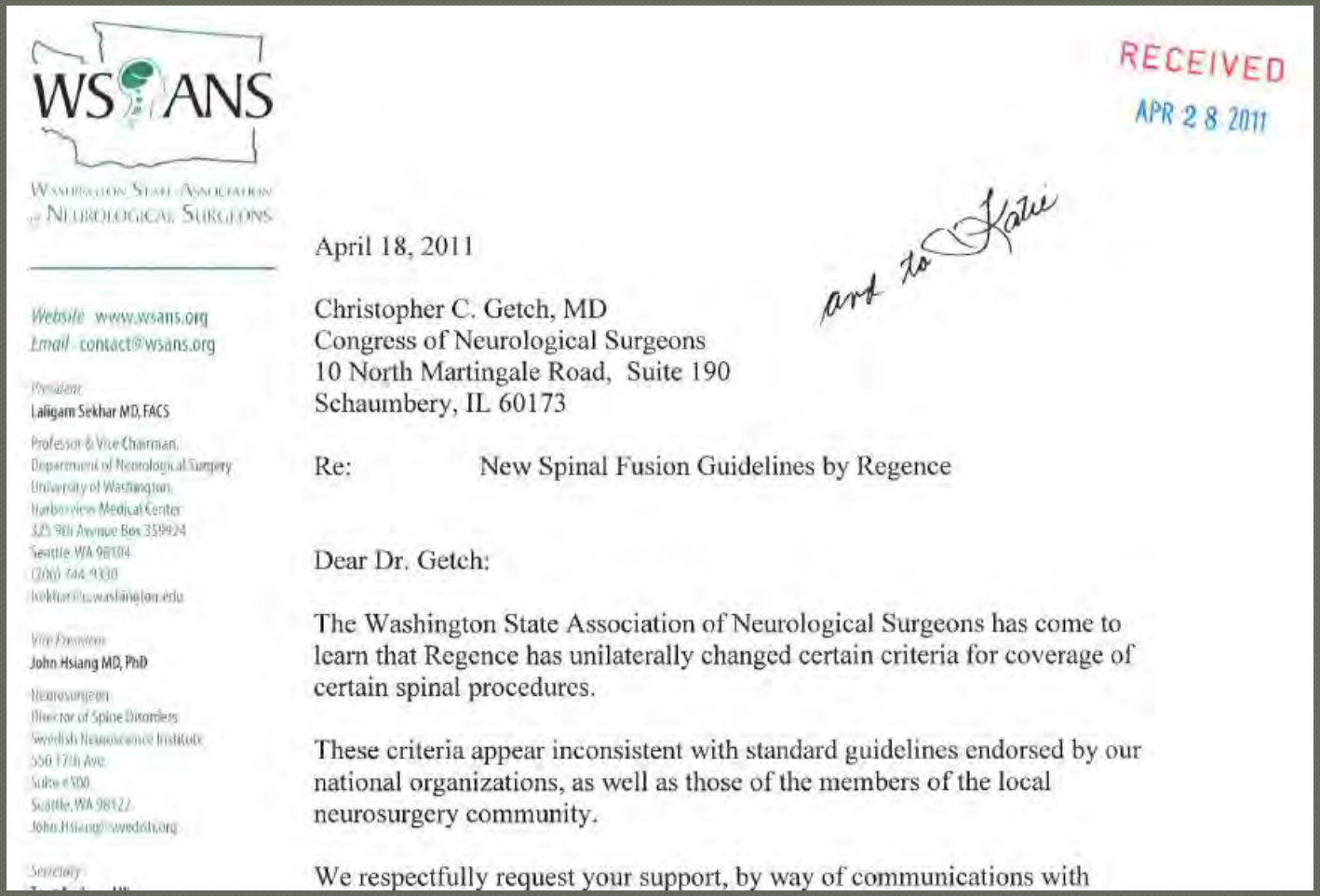
Regence BCBS



WSANS

Washington State Association of Neurological Surgeons

Website www.wsans.org
Email contact@wsans.org

President
Laligam Sekhar MD, FACS
Professor & Vice Chairman
Department of Neurological Surgery
University of Washington
Harborview Medical Center
325 9th Avenue Box 359924
Seattle, WA 98104
(206) 744-9330
lsekhar@u.washington.edu

Vice President
John Hsiang MD, PhD
Neurosurgeon
Director of Spine Disorders
Swedish Neuroscience Institute
550 17th Ave
Suite 650
Seattle, WA 98122
John.Hsiang@swedish.org

Secretary

RECEIVED
APR 28 2011

April 18, 2011

art to Katie

Christopher C. Getch, MD
Congress of Neurological Surgeons
10 North Martingale Road, Suite 190
Schaumbery, IL 60173

Re: New Spinal Fusion Guidelines by Regence

Dear Dr. Getch:

The Washington State Association of Neurological Surgeons has come to learn that Regence has unilaterally changed certain criteria for coverage of certain spinal procedures.

These criteria appear inconsistent with standard guidelines endorsed by our national organizations, as well as those of the members of the local neurosurgery community.

We respectfully request your support, by way of communications with

United

REVISED			
Title	**Effective Date**	**Summary of Changes**	**Coverage Rationale**
Artificial Total Disc Replacement for the Spine	Oct. 1, 2011	• Revised coverage rationale to indicate cervical artificial total disc replacement with FDA approved devices is now considered to be proven for the treatment of single level degenerative disc disease in skeletally mature patients • Updated description of	Cervical artificial total disc replacement is proven for the treatment of single level degenerative disc disease in skeletally mature patients when used with FDA approved implants. (FDA approved artificial discs include the Pro-Disc C, Prestige Cervical Disc and Bryan Cervical Disc.) Cervical artificial total disc replacement is

Washington State HTA

Washington State Health Care Authority
Health Technology Assessment
E-mail: shtap@hca.wa.gov

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), we would like to thank the Washington State Health Care Authority for the opportunity to comment on the draft Health Technology Assessment (HTA) regarding the use of recombinant human Bone Morphogenetic Protein (rhBMP2 and rhBMP7). We appreciate the efforts of your team in developing a very thorough review of the published literature reporting on the use of BMP as an adjunct to spinal fusion.

We believe rhBMPs are a comparably safe and effective bone graft alternative appropriate in patients with medical indications as determined by their treating surgeon. FDA approval of the on-label indications of rhBMP noted equivalent or superior fusion rates, shorter operative times, and decreased bone graft donor site complications. Our assessment of the literature would indicate that rhBMP's are appropriate bone graft options for single level anterior (ALIF) and posterior (PLIF) lumbar interbody fusion, and can also be considered an appropriate bone graft substitute in single-level posterolateral lumbar fusion.

Washington State HTA

HCA DIRECTOR SELECTS HEALTH TECHNOLOGIES

The HCA Director, in consultation with participating state agencies, has selected a group of health technologies that will undergo review and then be presented to the Health Technology Clinical Committee (HTCC) for coverage decisions. After reviewing the previously posted recommended technologies, agency input, committee input and public comments, the following 10 health technologies are selected for evidence based review beginning in 2012.

Selected Technologies

1. Prostate-specific Antigen (PSA) Testing
2. Ablation procedures for supraventricular tachycardia (SVT) including sinus tachycardia
3. Carotid artery stenting
4. Cervical level fusion for degenerative disk disease
5. Cochlear Implants (bi- or unilateral)
6. Fecal DNA testing for colon cancer screening
7. Hyperbaric Oxygen Therapy (HBOT) for wound care and brain injury
8. Intensity Modulated Radiation (e.g., Tomotherapy)
9. Cardiac Nuclear Imaging
10. Vitamin D testing for routine screening and monitoring

Washington State HTA

Wellpoint

WellPoint, Inc.
Medical Policy Questionnaire

January 17, 2012

Policy Number: SURG.00130
Policy Title: Annulus Closure After Discectomy

WellPoint, Inc. incorporates input from physicians practicing in relevant clinical areas along with other sources such as the peer-reviewed published medical literature, technology assessments, evidence-based consensus statements, and evidence-based guidelines from nationally recognized professional medical specialty societies as part of our process for developing and maintaining medical policies and clinical UM guidelines.

We are currently reviewing our medical on the topic of **Annulus Closure After Discectomy**. We are requesting your expert opinion regarding this topic and have developed a series of relevant questions presented in the table below.

We are seeking input addressing (1) the need for annular closure after discectomy and (2) the clinical impact for the use of devices designed for annular closure.

Wellpoint

WellPoint, Inc.
Medical Policy Questionnaire

January 25, 2012

Policy Number: SURG.00096
Policy Title: Surgical and Ablative Treatments for Chronic Headaches

WellPoint, Inc. incorporates input from physicians practicing in relevant clinical areas along with other sources such as the peer-reviewed published medical literature, technology assessments, evidence-based consensus statements, and evidence-based guidelines from nationally recognized professional medical specialty societies as part of our process for developing and maintaining medical policies and clinical UM guidelines.

We are currently reviewing our medical policy on the topic of **Surgical and Ablative Treatments for Chronic Headaches**. We are requesting your expert opinion regarding this topic and have developed a series of relevant questions presented in the table below.

We are seeking input for the surgical and ablative treatments of chronic headaches and specifically surgical and ablative treatments of occipital neuralgia.

We have designed our process to help you avoid duplication of effort in reviewing various entities' medical policies, with the goal of reducing your administrative burden. At the same time, your feedback and the feedback we receive from others on this topic may be shared with non-WellPoint entities, including a national association ("Association") and its constituents. This will allow your input to be considered as WellPoint, Inc. formulates its medical policy positions, which affect the more than 33

Wellpoint

DRAFT

0.00.00 – Intensity Modulated Radiation Therapy (IMRT): Central Nervous System Tumors

Description

Radiation therapy is an integral component in the treatment of most brain tumors. IMRT has been proposed as a method of radiation therapy that allows adequate radiation therapy to the tumor while minimizing the radiation dose to surrounding normal tissues and critical structures.

Background

Radiation therapy and brain tumors

The standard approach to the treatment of brain tumors depends on the type and location of tumor. For glioblastoma multiforme (GBM), treatment is multimodal, with surgical resection followed by adjuvant radiation therapy and chemotherapy. Radiation is usually delivered with 3-dimensional

Wellpoint

WellPoint, Inc.
Medical Policy Questionnaire

October 7, 2011

Policy Number: SURG.00127
Policy Title: Sacroiliac Joint Fusion

WellPoint, Inc. incorporates input from physicians practicing in relevant clinical areas along with other sources such as the peer-reviewed published medical literature, technology assessments, evidence-based consensus statements, and evidence-based guidelines from nationally recognized professional medical specialty societies as part of our process for developing and maintaining medical policies and clinical UM guidelines.

We are currently reviewing our medical policy on the topic of **Sacroiliac Joint Fusion**. We are requesting your expert opinion regarding this topic and have developed a series of relevant questions presented in the table below.

We are requesting your input concerning the indications for, types of procedures performed, and devices used during sacroiliac joint fusion.

We have designed our process to help you avoid duplication of effort in reviewing various entities' medical policies, with the goal of reducing your administrative burden. At the same time, your feedback and the feedback we receive from others on this topic may be shared with non-WellPoint entities, including a national association ("Association") and its constituents. This will allow your input to be considered as WellPoint, Inc. formulates its medical policy positions, which affect the more than 33

Wellpoint

September 16, 2011

Policy Number: SURG.00060
Policy Title: Implanted (Epidural and Subcutaneous) Spinal Cord Stimulators (SCS)

WellPoint, Inc. incorporates input from physicians practicing in relevant clinical areas along with other sources such as the peer-reviewed published medical literature, technology assessments, evidence-based consensus statements, and evidence-based guidelines from nationally recognized professional medical specialty societies as part of our process for developing and maintaining medical policies and clinical UM guidelines.

We are currently reviewing our medical policy on the topic of **Spinal Cord Stimulators (SCS)**. We are requesting your expert opinion regarding this topic and have developed a series of relevant questions presented in the table below.

We are sending the draft policy and questionnaire for input regarding new t-codes which will be effective and addressing percutaneous or open implantation of neurostimulator electrode array(s), subcutaneous (peripheral subcutaneous field stimulation).

We have designed our process to help you avoid duplication of effort in reviewing various entities' medical policies, with the goal of reducing your administrative burden. At the same time, your feedback and the feedback we receive from others on this topic may be shared with non-WellPoint entities, including a national association ("Association") and its constituents. This will allow your input to be considered as WellPoint, Inc. formulates its medical policy positions, which affect the more than 33

Wellpoint

January 19, 2012

Policy Number: 6.01.10
Policy Title: Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy

WellPoint, Inc. collects input from physicians practicing in relevant clinical areas on behalf of a national healthcare association ("Association") to support their processes for developing and maintaining medical policies.

We are currently reviewing the topic of **Stereotactic Radiosurgery and Stereotactic Body Radiation Therapy**. We are requesting your expert opinion regarding this topic and have developed a series of relevant questions presented in the table below.

The draft policy includes specific criteria for when **stereotactic radiosurgery** or **stereotactic body radiotherapy (SBRT)** may be considered **medically necessary**. Fractionated stereotactic radiosurgery and stereotactic body radiotherapy are considered **investigational**. We are interested in your input on the policy position, in particular, your comments on the use of fractionated stereotactic radiosurgery and stereotactic body radiotherapy.

We have designed our process to help you avoid duplication of effort in reviewing various entities' medical policies, with the goal of reducing your administrative burden. Your feedback and the feedback we receive from others on this topic will be shared with non-WellPoint entities, including the Association requesting this review and its constituents.

Wellpoint

WellPoint, Inc.
Medical Policy Questionnaire

September 19, 2011

Policy Number: SURG.00067
Policy Title: Percutaneous Spinal Procedures (Vertebroplasty, Kyphoplasty and Sacroplasty)

WellPoint, Inc. incorporates input from physicians practicing in relevant clinical areas along with other sources such as the peer-reviewed published medical literature, technology assessments, evidence-based consensus statements, and evidence-based guidelines from nationally recognized professional medical specialty societies as part of our process for developing and maintaining medical policies and clinical UM guidelines.

We are currently reviewing our medical policy on the topic of Percutaneous Spinal Procedures (Vertebroplasty, Kyphoplasty and Sacroplasty). We are requesting your expert opinion regarding this topic and have developed a series of relevant questions presented in the table below.

We are seeking input for the medically necessary and investigational/not medically necessary criteria listed, and specifically, the use of percutaneous vertebroplasty or kyphoplasty in the cervical, lumbar or thoracic region for treatment of traumatic or steroid-induced vertebral fracture with persistent debilitating pain, refractory to standard medical therapy.

WPS

Stereotactic Computer Assisted Volumetric And/Or Navigational Procedure (L29586)

Contractor Information

Contractor Name	Contractor Number	Contractor Type
Wisconsin Physicians Service Insurance Corporation	00951, 00952, 00953, 00954, 52280, 05101, 05201, 05301, 05401, 05102, 05202, 05302, 05402	Carrier - FI - MAC

Back to Top

LCD Information

Document Information

LCD ID Number
L29586

LCD Title
Stereotactic Computer Assisted Volumetric and/or Navigational Procedure

Contractor's Determination Number
GSURG-050

AMA CPT/ADA CDT Copyright Statement
CPT codes, descriptions and other data only are copyright 2010 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply. Current Dental

Primary Geographic Jurisdiction

Oversight Region

Original Determination Effective Date
For services performed on or after 08/16/2009

Original Determination Ending Date

Continuing Issues

- Backlash for techniques and procedures that we are unable to support
  - Pressure from colleagues
  - Legal implications
  - Industry issues
- Need for multisociety consensus
- Need for multisociety organization
  - "Common ground"
- Work load and resource management

AMA/CPT Issues: Changes to Policy and Lobbying

William Sullivan, MD
Coding Committee Co-Chair
RUC Advisor
North American Spine Society

Disclosures

- No Financial Disclosures

AMA/CPT Process Concerns

- Changes in CPT process
  - New statements from CPT related to Industry submission of proposals: Draft statement early 2012
  - AMA/CPT proposals to change criteria
    - Less involvement from specialty societies
      - Encouraged, but not required to participate
    - Lower level of evidence needed for Cat I code
      - Less literature, not US based, lower level of evidence
    - Requirements from AMA/CPT for societies to align criteria for code submission

AMA/CPT Process Concerns

- Increased reports of Industry in contacting society volunteer committees, as well as direct contact with society leadership
- Increased Industry involvement
  - Direct submission
  - Non-uniform disclosure policies
    - Increased stock value with Cat I code?
  - Level of evidence requirements
    - Changes proposed related to evidence
    - Evidence selection bias
  - Inclusion of off-label uses (e.g. BMP) in proposals

AMA/CPT Process Concerns

- Definitions of “Lobbying” not clear
- Threat of Legal Action?
- Category III codes felt to be death knell

- Changes to CPT code criteria to be voted on at October Editorial Panel meeting

Does the AMA represent the interests of spine care?

August 2010

Charles Mick, MD

Pioneer Spine and Sports

Northampton, MA

AMA CPT Issue and Industry Lobbying

August 2012

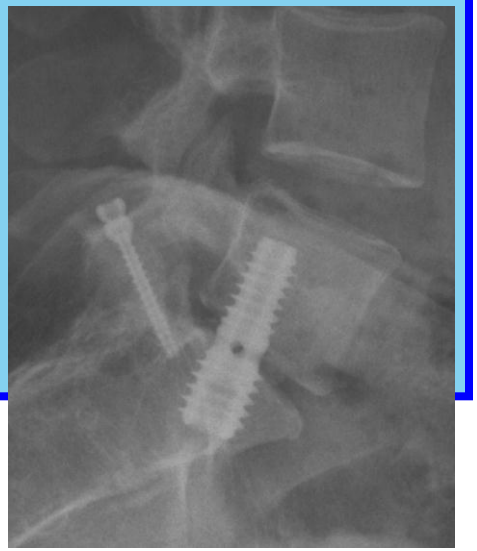
Charles Mick, MD

Disclosures

- Nothing to disclose

History of Trans1 / AXIAlif

- 2002- 510K clearance FDA
- 2005- US marketing begins
- 2009- Cat III code
  - 0195T Arthrodesis, pre-sacral interbody technique, including instrumentation, imaging(when performed), and discetomy to prepare interspace, lumbar; single interspace



History of Trans1 / AXIAlif

- 2010- Trans1 requests Cat I code
- Oct 2011- Trans1 submits Cat I application
  - CPT rejects proposal
    - Literature
    - Language

History of Trans1 / AXIAlif

- Feb 2012 Trans1 resubmits application with modifications
  - Approved by CPT
  - No society support
  - Bundled code
    - Included off label use of BMP in studies
  - Vigorous lobbying campaign

History of Trans1 / AXIAlif

- March 2012 CPT proposes changes to CPT process and criteria
- April 2012 Cat I code presented at RUC
  - Societies have no recommendation for work
- April 2012
  - NASS, AAOS, AANS/CNS appeal to AMA Board of Trustees

History of Trans1 / AXIAlif

- May 2012 Societies meet with CPT executive committee
- June 2012
  - Resolutions submitted to AMA House of Delegates; NASS and AANS/CNS

AMA-NASS

- RESOLVED, That our American Medical Association direct the CPT Editorial Panel to reaffirm and enforce the current CPT process **requiring support from at least one specialty society Advisor before a proposal may be considered before the full Panel** and include this requirement in the CPT Category I and Category III code criteria (Directive to Take Action).

AMA –AANS/CNS

- RESOLVED that that CEJA review the ethical implication of industry involvement in the CPT editorial process; (Directive to Take Action)
- RESOLVED that, similar to the RUC, and subject to the results of the CEJA inquiry, the our AMA Board of Trustees request that the AMA CPT Editorial Board ban all industry participation in the CPT editorial process; (Directive to Take Action) and be it further
- RESOLVED that our AMA Board of Trustees direct the CPT Editorial Panel to re-affirm policy that "All proposed changes of the *CPT* codebook will be considered by the CPT Editorial Panel with consultation of appropriate medical specialty societies"
- RESOLVED that all new or revised Category I CPT Codes must have the support of at least one Medical Specialty Society that is recognized by our AMA and seated in the HOD before the code change can go into effect. (Directive to Take Action)

AMA- NASS

- RESOLVED, That our American Medical Association encourage the CPT Editorial Panel to **implement and enforce a uniform disclosure and confidentiality policy for all participants** in the CPT process. (Directive to Take Action)

AMA

- June HOD meeting
  - Resolutions prevented from coming to the full house for debate/vote
- July 2012 NASS requests meeting with AMA Board
  - Rejected

AMA

- August 2012 CPT reviews lobbying by Trans1 and finds it acceptable
  - Inappropriate lobbying requires “explicit or implicit coercion, intimidation or harassment”
- August 2012- SIBone
  - Will history repeat itself?

AMA

- Concerns
  - ⬇role of medical societies at CPT
  - ⬆influence of industry
  - ⬆aggressiveness of lobbying
  - Concern re Cat III codes
  - ⬆ threat of legal measures
  - ⬇ quality of evidence for Cat I code
  - Inclusion of off label products in bundled codes
  - Non uniform disclosure policy

- "The voice of medicine"
- 100,000 – 240,000 members
- 1045 employees
- $268 million budget (2009)
  - $42 million membership
  - $210 business operations
    - $70 million books

The Path Forward
possible future actions

- Let CPT become purely descriptive
  - Submit code proposals and let CPT decide the category
  - Concentrate on coverage decisions with insurance carriers
- Continue discussion with leadership
  - CPT, AMA BOD, HOD
- Appeal to CMS
  - Withdraw from CPT process
- Appeal to the public/press

AMA CPT

- Patients
- Members
- Innovation/New technology
- Industry

AMA

- Ask yourselves two questions-
  - Are the actions at CPT jeopardizing patient care and well being?
  - Does the AMA's financial conflict of interest jeopardize patients?

Thank you

Milliman Guidelines and Payer Policies

AANS/CNS Committee For Payer and Policy Responses

Joseph S. Cheng, M.D., M.S.

Chairperson

AANS/CNS SECTION ON DISORDERS OF THE SPINE AND PERIPHERAL NERVES

Anthem.
Health. Join In.

CUSTOMIZATIONS TO MILLIMAN CARE GUIDELINES®
16th EDITION

Issue Date:	Original Date:
February 27, 2012	February 27, 2012

NOTE:

- *This document provides a high level summary of customizations and modifications made to Milliman Care Guidelines® (hereinafter referred to as "Customized Guidelines").*
- *Customized Guidelines are available on request.*
- *Benefit plans vary in coverage and some plans may not provide coverage for certain services discussed in the Customized Guidelines. Coverage decisions are subject to all terms and conditions of the applicable benefit plan, including specific exclusions and limitations, as well as applicable state and/or federal law. The Customized Guidelines do not constitute plan authorization or a guarantee of payment, nor are they an explanation of benefits.*
- *We reserve the right to review and modify the Milliman Care Guidelines or Customized Guidelines at any time.*
-

What We Are Up Against

GENERAL FIRM INFORMATION

Milliman is a financial investment advisory firm headquartered in Seattle, Washington. The firm manages 162 accounts totaling an estimated $22.6 Billion of assets under management. Milliman's 2,000 employees help advise 100+ clients.

Firm CRD #	112245
Registered By	SEC Registered Compare SEC Registered Investment Advisors
SEC Number	801-33315
Company Legal Name	Milliman, Inc.
Website	Milliman (WWW.MILLIMAN.COM)

FIRM ASSETS

Total Assets Under Management	$22.6 Billion
Total Number of Accounts	162
Average Balance in Accounts	$140 Million
Discretionary Assets Under Management	$30.1 Million
Total Number of Discretionary Accounts	2
Non-Discretionary Assets Under Management	$22.6 Billion
Total Number of Non-Discretionary Accounts	160
Assets of 100 Million or More?	Yes

Cervical Fusion, Anterior

ORG: S-320 (ISC)

Link to Codes

Milliman Care Guidelines® Inpatient and Surgical Care 14th Edition

- Procedure may be indicated for **1 or more** of the following(1)(2)(3):
  - Unstable traumatic anterior column fracture, especially burst fracture(4)(5)(6)
  - Cervical radiculopathy and **ALL** of the following[A](3)(10):
    - MRI or other neuroimaging demonstrates nerve root compression due to disk herniation(11)
    - Unremitting radicular pain or progressive weakness secondary to nerve root compression
    - Failure of conservative therapy indicated by persistent signs or symptoms despite treatment with **1 or more** of the following[B](11)(12):
      - Nonsteroidal anti-inflammatory drugs (NSAIDs)
      - Nonnarcotic analgesics (eg, tricyclic antidepressants, anticonvulsants)
      - Cervical collar
      - Physical therapy(13)
      - Exercise program
      - Oral corticosteroids
  - Multilevel spondylotic myelopathy indicated by **ALL** of the following(3)(14)(15)(16):
    - Signs or symptoms of myelopathy indicated by **1 or more** of the following:
      - Clumsiness of hands
      - Bowel or bladder incontinence
      - Frequent falls
      - Hyperreflexia
      - Hoffmann sign[C]
      - Increased tone or spasticity
      - Gait abnormality
      - Positive Babinski sign
      - Other clinical signs or symptoms of myelopathy
    - MRI or other neuroimaging demonstrates cord compression from herniated disk or osteophyte
  - Ossification of the posterior longitudinal ligament at 1 to 3 levels associated with myelopathy(14)(17)
  - Degenerative cervical spondylosis with kyphosis causing cord compression
  - Traumatic disk herniation associated with myelopathy
  - As part of a procedure for primary or metastatic cervical spine tumor causing pathologic fracture, cord compression, or instability[D](18)

Operative Status Criteria

Return to top of *Cervical Fusion, Anterior - ISC*

- Ambulatory: Criteria include 1- or 2-level fusions, fusions at or below C4-5, structural allograft, estimated operative time less than 2 hours, no myelopathy or subjectively large neck, and presence of an appropriate discharge environment.(26)(27)(28)
- Inpatient: Multilevel fusions may require an overnight stay.

Preoperative Care Planning

Return to top of *Cervical Fusion, Anterior - ISC*

- Preoperative care planning needs may include:
  - Preoperative evaluation, including (29):
    - Primary care, neurologic, or orthopedic consultation to assess baseline function and stabilize other deformities or underlying comorbidities
    - Preoperative counseling for patient with such psychosocial factors as unrealistic expectations, clinical depression, work aversion, or use of illicit drugs
    - Routine preoperative evaluation. See Preoperative Education, Assessment, and Planning Tool.
  - Diagnostic test scheduling, including(3)(30):
    - Neck x-rays, including:
      - Anterior-posterior and lateral views to assess fracture or alignment
      - In the absence of trauma, flexion-extension views to assess for instability
    - MRI for evaluation of soft tissues and spinal cord

Lumbar Fusion

ORG: S-820 (ISC)

Link to Codes

Milliman Care Guidelines® Inpatient and Surgical Care 14th Edition

- Procedure[A] may be indicated for **1 or more** of the following(5)(6)(7):
  - Spinal fracture with **1 or more** of the following(4):
    - Spinal instability
    - Neural compression
  - Lumbar spinal stenosis[B] with **ALL** of the following(1)(11)(12):
    - Associated lumbar spondylolisthesis demonstrated on plain x-rays
    - Clinically important findings indicated by **1 or more** of the following:
      - Progressive or severe symptoms of neurogenic claudication
      - Back pain, neurogenic claudication symptoms, or radicular pain associated with **ALL** of the following:
        - Significant functional impairment
        - Central, lateral recess or foraminal stenosis demonstrated on imaging (eg, MRI, CT, myelography)
        - Failure of at least 3 months of conservative care
  - Spondylolysis[C] with **1 or more** of the following(13)(15):
    - Progressive spondylolisthesis with neurologic compromise
    - Spondylolisthesis with **ALL** of the following(16)(17):
      - High-grade (ie, 50% or more anterior slippage) spondylolisthesis demonstrated on plain x-rays
      - Back pain, neurogenic claudication symptoms, or radicular pain from lateral recess or foraminal stenosis
      - Significant functional impairment
      - Failure of at least 3 months of conservative care

Lumbar Fusion

ORG: S-820 (ISC)

Link to Codes

Milliman Care Guidelines® Inpatient and Surgical Care 14th Edition

Return to top of *Lumbar Fusion - ISC*
See Extended Stay definition

Minimal (a few hours to 1 day), Brief (1 to 3 days), Moderate (4 to 7 days), and Prolonged (more than 7 days).

- Extended stay beyond goal length of stay may be needed for(3)(30)(31):
  - Pathologic fracture: expect brief stay extension.
  - Severe scoliosis: expect brief stay extension.
  - Spinal abscess or osteomyelitis: expect brief to moderate stay extension.
  - Severe deficit or injury
    - Patients with significant neurologic compromise or multiple injuries will require longer acute care and recovery times.
    - Stay extension varies depending on injury.
  - Dural tear
    - Anticipate possible CSF drainage and surgical repair.
    - Expect brief to moderate stay extension.
  - Intraspinal hemorrhage
    - Intraspinal hemorrhage may need surgical repair.
    - Expect brief to moderate stay extension.

Patient Name:	[redacted]	**Enrollee Name:**	[redacted]
Enrollee ID:	5831000003538	**Employer:**	K-VA-T (Food City)
Third Party Administrator:		Wells Fargo	
Facility:		[redacted]	
Case Reference Number:	110128A294703	**Admission Date:**	02/03/2011
Number of Days Approved:	3	**Number of Days Denied:**	1
Date(s) Denied:		02/06/11	
Principal Reason for Denial:		Appropriate for lower level of care	
Specific Medical & Scientific Reason(s) for Denial:		Appropriate for lower level of care based on documentation submitted.	
Physician Reviewer License#-State:		36601-TN, 0101233267-VA	
Physician Reviewer Title:		Medical Director	
Date of Review Decision:		02/10/2011	

Dear [redacted]

After careful review of medical information regarding the above-referenced inpatient stay, a portion of the stay has been denied for the reasons stated above. Upon request from you, the ordering physician(s), or facility, the specific review criteria upon which the decision was based will be provided in writing at no cost to you.

This denial decision does not require that you leave or be discharged from the hospital, as the decision to discharge should be made by your physician only. As a result of contractual obligations with this facility, there may be no financial obligation on your part for any denied days. A copy of this denial will be mailed to your physician, the facility, and the third-party administrator.

Past Experience

Entrepreneur

Click to Print This Page

Milliman USA Faces Physicians' Lawsuit.(Pediatric Health Status Improvement and Management charged with misappropriation of phys

By THERESA DEFINO | Oct, 2001

Pediatric News

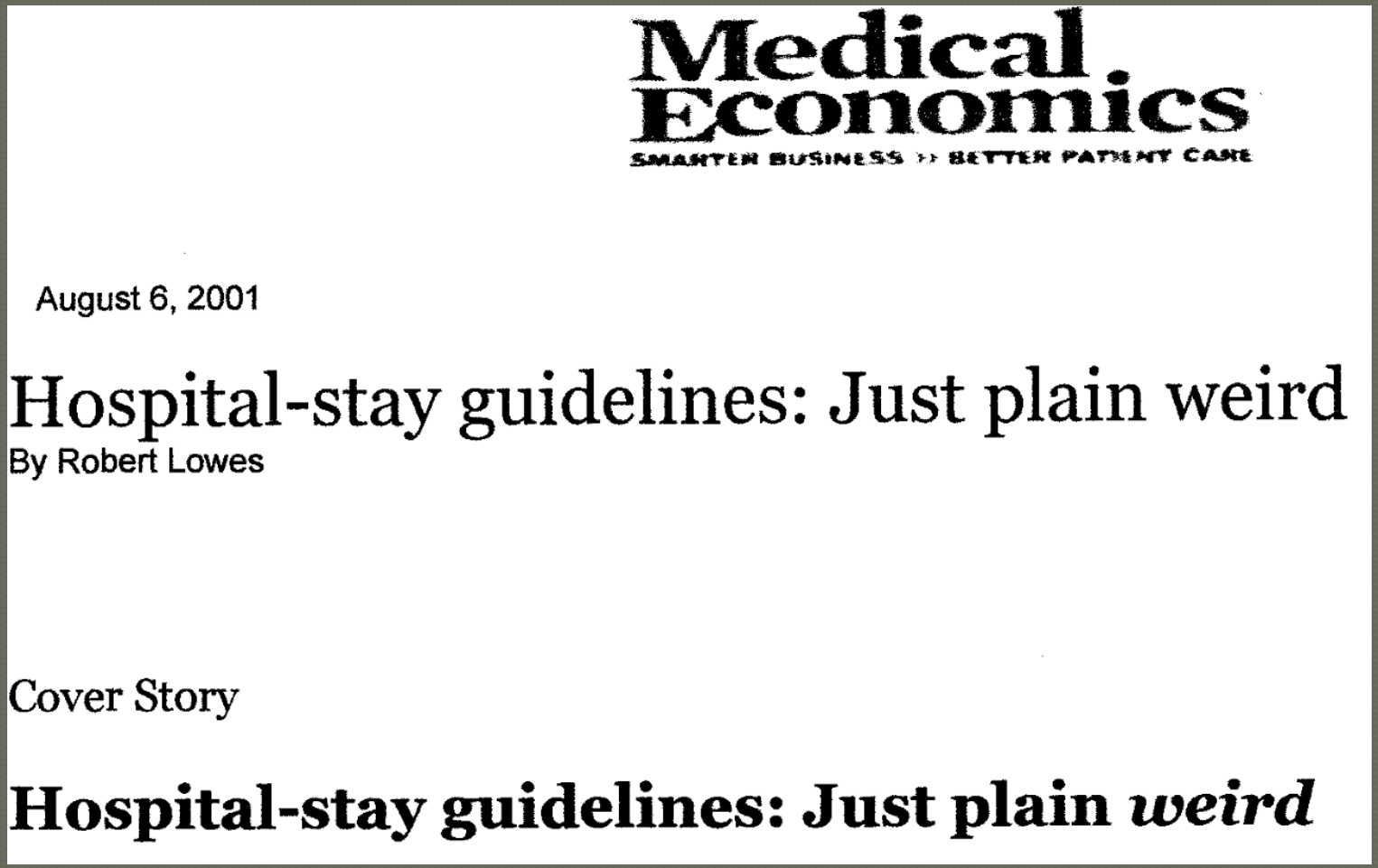
Before Dr. Thomas Cleary got mad enough to hire a lawyer, the pediatric infectious disease specialist was most at home discussing the vagaries of Escherichia coli and Shigella.

But 3 years after filing a lawsuit that alleges misappropriation of his name to sell controversial patient care guidelines, the physician finds himself equally versed in the intricacies of libel law--and at the center of the backlash against the use of guidelines.

At its narrowest, Dr. Cleary's case, now pending in the 333rd District Court in Harris County, Tex., is about compensating him and three other pediatricians for what they say is damage to their reputations caused by their association with a volume published in December 1998 by Seattle-based Milliman USA, called "Pediatric Health Status Improvement and Management."

In a broader sense, "this issue goes way beyond the use of my name,' says Dr. Cleary, a professor at the University of Texas, Houston. "The guidelines are not based on good medical practices. They really represent substandard care."

Past Experience



Medical Economics

SMARTER BUSINESS >> BETTER PATIENT CARE

August 6, 2001

Hospital-stay guidelines: Just plain weird

By Robert Lowes

Cover Story

Hospital-stay guidelines: Just plain *weird*

Past Experience (1998)

An Analysis of 25 Milliman & Robertson Guidelines for Surgery

Data-Driven *Versus* Consensus-Derived Clinical Practice Guidelines

Robert Rutledge, MD, FACS

From the University of North Carolina School of Medicine, Chapel Hill, North Carolina

Summary Background Data
Managed care guidelines such as those by Milliman & Robertson (M&R) are being implemented with increasing frequency. Many fellows of the American College of Surgeons have raised concerns that the targets set by the M&R guidelines are too aggressive. Uninformed attempts to reach these targets may harm patients. The primary hypothesis of this study was that many of the M&R guidelines are at wide variance from the actual length of stay of patients treated for these diseases.

Methods
Data for the determination of the present practice of care for patients in 25 M&R guidelines were obtained from the hospital discharge data base for North Carolina for 1996. Twenty-five of the M&R guidelines were compared to the actual patient mean, mode, and median length of stay.

Results
In 8 of the 25 patient groups, the difference between the actual mean length of stay and M&R guidelines exceeded 5 days.

Conclusions
Many of the M&R guidelines were found to be at wide variance from the actual length of stay of patients treated for these diseases in North Carolina. For many patients, the M&R guidelines are not applicable. Applying them in an uninformed way—in other words, discharging patients from the hospital too early—may hurt some patients. This study should not be interpreted as a criticism of the trend to use guidelines in general; rather, it should be considered a cautionary note that all guidelines must be reviewed scientifically to determine their soundness, applicability, and credibility.

Guidelines Versus AUC

Milliman Healthcare Reform Briefing Paper

How Hospitals Can Successfully Implement Evidence-based Guidelines

Milliman

Patty Merola
MHA

Rodger C. Hopkins
MA, MHA

Despite all the dissonance that characterized the healthcare reform debate leading up to the new law's passage in March, a few principles seem to have attracted general agreement: first, the fact of too much waste in American healthcare; second, that we need higher-quality care; and third, that science and clinical best practice ought to play some role in the overall fix of healthcare. While the idea of improving quality and efficiency may seem paradoxical, these improvements are actually complementary.

the culture, influence preexisting care preferences, and bring key stakeholders on board? How does a hospital or other provider organization that is not currently built around evidence-based medicine begin to tap into this collective clinical intelligence?

This paper will look specifically at the challenges of implementing evidence-based guidelines and fostering the positive changes they can bring. With or without reform, many of the goals stated at the outset of the reform process are embodied in this idea of

Guidelines Versus AUC

- Guidelines
  - Available published evidence regarding the efficacy of a procedure or service.
  - Does not determine **who** should perform or **in which patients** it should be performed on.
- Appropriate Use Criteria (AUC)
  - Specify when it's appropriate to perform a procedure (patient selection).
  - Not consensus documents, but needs consensus when literature is lacking
- Neither are substitutes for sound clinical judgment and practice experience.

Strength in Numbers

March 8, 2011

Lonny Reisman, MD
Aetna Chief Medical/Clinical Officer
151 Farmington Avenue
Hartford, CT 06156
860-273-0970

Proposal

- Multisociety Support to Review Milliman Guidelines
  - Physician representatives
  - Financial support of external system review
- Address obvious errors and shortcomings of Milliman Guidelines
- Larger Scale Proposal
  - Develop AUC's
  - Develop pre-/post-surgical pathways

Coverage Task Force

Christopher M. Bono, MD

Treasurer, North American Spine Society
Associate Professor of Orthopaedic Surgery
Harvard Medical School
Chief, Orthopaedic Spine Service
Brigham and Women's Hospital
Boston, Massachusetts

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MGH SPINE BWH BOSTON,MA

Insurance Coverage for Spine Has Become Restricted

- "investigational"
- "not covered"
- fulfill criteria

UnitedHealthcare®
Healing health care. Together.®

BlueCross BlueShield

Aetna™
Turning promise into practice™

Neighborhood Health Plan

BWH
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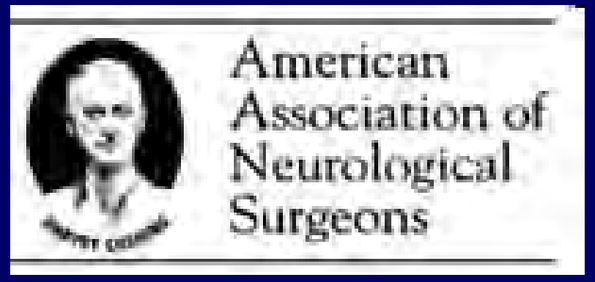
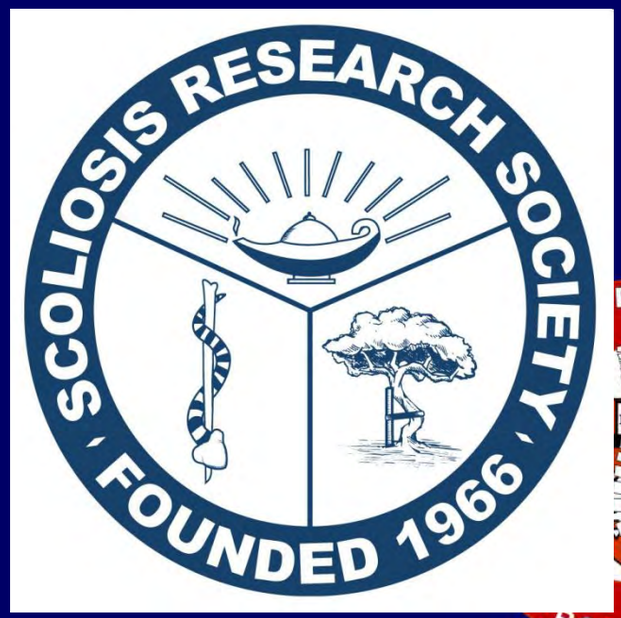
Societies' Role?

- respond/react





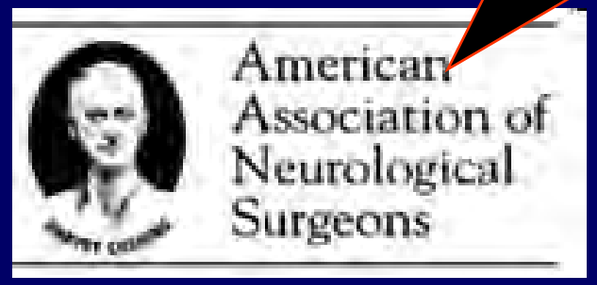
Societies' Role?

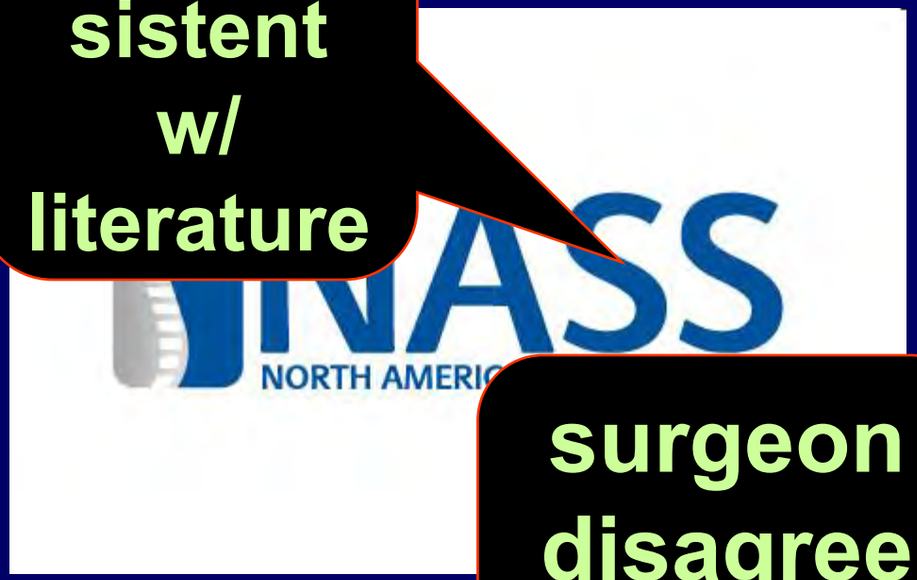
- respond/react
- ***at 1st, individually...***

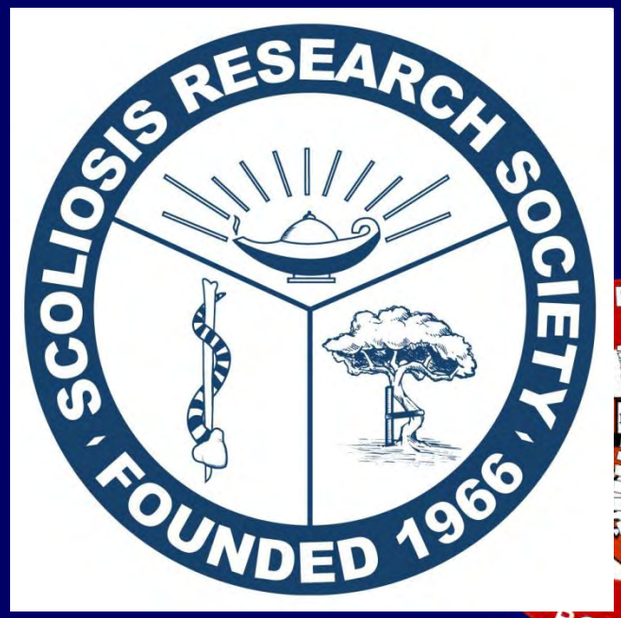
policy is incon-sistent w/ literature

unfair, should be covered

surgeon disagree w/ policy





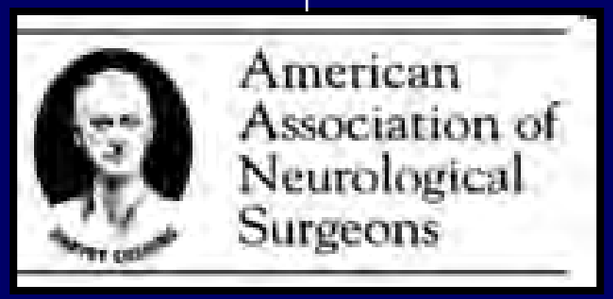


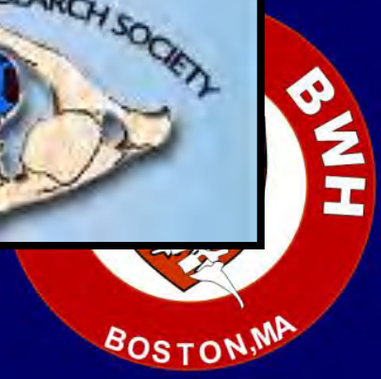
Societies' Role?

- respond/react
- at 1st, individually...
- ***on occasion, <u>TOGETHER</u>***

•2006 MCAC Lumbar fusion

•North Carolina BCBS 2010





Societies' Role?

- respond/react
  - at 1st, individually...
  - on occasion, TOGETHER

Bottom Line: has always been REACTIVE

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It's time to be PROACTIVE

- **How?**
- **AUC (Charlie Reitman et al)**
- **Review and Recommendation (deceased)**
- **New Coverage Task Force at NASS**

codename: "Proactive PERC"

[not to replace current PERC (Chris Kauffman et al)]

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SPINE MGH BWH BOSTON,MA

This is how we respond so far...

- **invited (required?) to review proposed coverage policy**
- **respond w/in their construct**

Fax:	617-732-6397
Date:	2-23-2011

Conflict of Interest	Yes	No	Comments
Do you have now, or have you had previously, any commercial or research relationship with any company or program which provides or markets products dealing with minimally invasive lumbar interbody fusion? If so, please disclose that relationship.	X		In past years (greater than 2 years ago), I had consulting agreements with companies that sell minimally invasive lumbar fusion products.

Your input will be shared with the applicable medical policy committee(s) when this topic is presented. Please indicate if WellPoint, Inc. may release the following points of information to the committee(s) and non-WellPoint entities, including a national Association.

	Yes	No	Comments
Name of your Academic/Hospital Affiliation(s)	x		
Your Name	x		

NASS

Policy Number: 7.01.115
Policy Title: Minimally Invasive Lumbar Interbody Fusion
Definitions of Medically Necessary and Investigational included in Exhibit I

	Yes	No	Comments
General questions:			
Is the POLICY POSITION clear and supported by the medical evidence in the peer reviewed medical literature? If no, please comment.		X	We agree with the policy position for minimally invasive surgery (MIS) approaches for ALIF, PLIF, and TLIF being medically necessary. There is ample literature regarding these procedures. We also agree about the policy position for laparoscopic ALIF and AxiaLIF being investigational. For the former, this has been shown to have an unacceptably high rate of complications as compared to other "mini open" techniques for ALIF. As for AxiaLIF, this is a novel technique that utilizes a surgical corridor that has no previously validated or evaluated analogue. We disagree with the policy position the procedures listed as LTIF, XLIF, and DLIF. For clarification, these 3 procedures are technically analogous to each other, in that there are trans-psoas lateral approaches. They also utilize a similar surgical corridor to a standard open anterolateral approach to the lumbar spine. In a previous letter developed by NASS (**attached-see below – pages 8-11**), a strong argument is made that the so-called LIF procedures (lateral interbody fusions) are sufficiently similar to the standard approach for ALIF that they should NOT be considered investigational. That being said, there

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This is how we respond so far...

- **invited (required?) to review proposed coverage policy**
- **OR via a letter**

March 1, 2011

Maggie Hackett, RN, MBA, CPHQ
Medical Services Administrator, Medical Policy
Premera Blue Cross
7001 - 220th Street, SW, Building 1
Mountlake Terrace, WA 98043

Re: Lumbar Fusion and Discography Corporate Medical Policy

Dear Ms. Hackett:

The North American Spine Society (NASS) would like to thank you for the opportunity to review your Lumbar Fusion and Discography corporate medical policy. We understand that this is a confidential document and have treated it as such. In addition, we hope that you perceive our comments to be constructive and worthwhile in constructing a final policy.

Under the policy heading "Lumbar Fusion-Structural Conditions", we agree with the determination that lumbar fusion for vertebral tumors, vertebral infection, spinal fractures with instability or neurological impairment, instability caused by aggressive lumbar decompression for a structural problem, pseudarthrosis (as described), and spinal deformity. We also agree that unstable spondylolisthesis is a medically necessary indication for lumbar fusion. However, the definition of unstable as requiring greater than 4 mm of translation motion on flexion/extension views is overly stringent and excludes a large majority of adult patients with spondylolisthesis. While there are many types of spondylolisthesis, the two most common in adult patients is isthmic (in which there is a chronic stress fracture of the pars interarticularis) and degenerative spondylolisthesis. In degeneration spondylolisthesis, it is well accepted that if a decompression, such as a laminectomy, is to be performed than adding fusion to the procedure results in better clinical outcomes (Herkowitz and Kurz, 1991). This scenario may fall under the "instability caused by aggressive lumbar decompression" bullet as listed in the current policy. However, this needs to be clarified as such patients do not have dynamic instability, i.e. 4 mm of translational change on flexion-extension views. Further more, most adult patients with isthmic spondylolisthesis do not have dynamic changes on flexion-extension views, but the literature strongly supports fusion for this indication if nonoperative treatment has failed (Moller and Hedlund, 2000).

We, therefore, suggest that instead of the wording "unstable spondylolisthesis" the policy should denote "dynamic

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BOSTON, MA

Coverage Task Force Goal

- **give them what they want BEFORE they ask for it**
- **use similar format:**
  - **Procedure X should be covered/in following situations**
  - **Rationale (evidence review, physician experience and judgement)**

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Challenges for Task Force

- **topic selection**
- **topic assignment**
- **MULTI-SOCIETY INVOLVEMENT? POSSIBLE?**

DISCUSSION

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Thank you

BWH
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