MEETING MINUTES
OF THE
CENTERS FOR MEDICARE AND MEDICAID SERVICES
MEDICARE COVERAGE ADVISORY COMMITTEE

Spinal Fusion for the Treatment of Low Back Pain Secondary to Degenerative Disc Disease

November 30, 2006

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland

Medicare Coverage Advisory Committee

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Attendees

Alexander H. Krist, M.D.
Chairperson

Michelle Atkinson
Executive Secretary

Voting Members
Mark V. Boswell, M.D., Ph.D.
Barbara D. Boyan, Ph.D.
Kim J. Burchiel, M.D.
A. Mark Fendrick, M.D.
David R. Flum, M.D., M.P.H., F.A.C.S.
Jeffrey G. Jarvick, M.D., M.P.H.
Stephen L. Onda, M.D.
Laxmaiah Manchikanti, M.D..
John S. Kirkpatrick, M.D.

HCFA Liaison
Steve Phurrough, M.D., M.P.A.

Consumer Representative
Charles J. Queenan, III

Industry Representative
Kim K. Kuebler, M.N., R.N.

Guests
Tom Faciszewski, M.D.
Jon D. Lurie, M.D., M.S.

Thursday, November 30, 2006, 8:05 a.m.

The Medicare Coverage Advisory Committee met on November 30, 2006, to discuss the evidence, hear presentations and public comment, and make recommendations regarding spinal fusion for the treatment of low back pain secondary to lumbar degenerative disc disease in various Medicare populations.

The meeting began with a reading of conflict of interest issues and an introduction of the Committee.

CMS Summary, Presentation of Voting Questions, and Clinical Background. A CMS representative presented the panel with the questions to be considered by the panel, and also presented an overview of the clinical history and CMS coverage regarding spinal fusion.

Presentation of the Technology Assessment. The results of a technology assessment (TA) performed by the Duke University Center for Clinical Health Policy Research and Evidence-Based Practice Center were presented. The TA focused on the following question: In patients 65 years of age or older with degenerative disc disease (DDD) and/or degenerative joint disease of the lumbar spine, what is the evidence regarding indications and outcomes including adverse events (overall health benefit) of lumbar spinal fusion as compared to non-surgical conservative treatment/management or other surgical strategies? The review found no evidence from randomized controlled trials (RCT) that directly compared lumbar spinal fusion with non-surgical treatments in populations $\geq$ 65 years old. There is an absence of systematic evaluation of efficacy or safety of lumbar spinal fusion in the elderly and the elderly may be different from younger patients due to age related changes in the spine and the existence of comorbid

conditions. Four non-US RCT's in the middle-aged population were identified that studied fusion for axial lumbar pain vs rehab/PT, all with posterior or mixed fusion procedures. These RCT's failed to demonstrate definitive improvements compared with rehabilitation in the Oswestry Disability Index (ODI). Most of the available data is from series/cohort studies. Some of the limitations of fusion studies were: studies were often procedure-based rather than indication based; fusion studies mostly included middle-aged people, not the elderly; the main outcomes often were not patient-centered or well-measured; non-surgical controls were not standardized; and, there was variation in defining the clinical condition. (The panel was provided the full text of the draft TA for their review.)

Additional Presentations. The panel heard a presentation by the Chairman of Orthopedics at the University of California at San Diego on the effects and clinical outcomes of fusion for low back pain. Some of the problems in dealing with axial low back pain are: symptoms are often vague; difficult to make a differential diagnosis; questionable etiology; limited diagnostic tools; and the lack of consistent use of any/all measurement instruments. Some of the challenges identified were: lack of RCT's; lack of clear diagnosis/indications in some cases; increasing number of spinal devices cleared by the Food and Drug Administration; ethical issues; and, the increase number of fusion in the over 60 year old population who are living longer, have more active lifestyles and expectation. Conclusions were that fusion has a role in treatment of discogenic back pain, but that better outcomes would be achieved with stricter selection criteria, including failed non-operative care and more preoperative instability. Additionally, criteria for low back pain surgery should include failed non-operative care ; x-rays or MRIs showing one or two levels maximum degenerative disc disease; a discogram which reproduces the pain

at the same one or two levels; and a patient who is willing to undergo a rigid procedure to his back. Improvement would be seen from the current 90-plus percent fusion rates and 60 to 80 percent clinical improvement rates with better diagnostic tools to target the pathophysiologic cause and assess the pain. Rather than looking for an ideal study, efforts should be directed toward a realistic study.

Next, the panel heard a presentation from an orthopedic surgeon at the University of Washington relating the variation in utilization, efficacy and safety in surgery for chronic back pain. The presenter noted that there are significant variations in back surgery (fusion) across the US - up to a 20X difference for fusion. There is an increase trend in the number of spinal fusions performed in this country. Conclusions from this presentation were that lumbar fusion rates have gone up despite any real compelling evidence that fusion is a much better procedure than other alternatives; fusion for chronic back pain compared to rigorous nonoperative treatment like that in the Brox and Fairbank study is probably equivalent, while compared to routine care available in the U.S., fusion is probably better; safety data are limited; advances in technology at least have improved the reoperation rates with fusion; and financial conflicts have a bearing

Scheduled Public Comments. A representative of a device manufacturer, an individual spine surgeon, and three speakers making a joint presentation on behalf of six professional societies, addressed the panel.

Open Public Comments. Three members of the public who were not previously scheduled addressed the panel.

Questions to Presenters. The panel engaged in an extensive period of clarifying questions to various presenters. Some of these discussions centered on the following topics. 1.) The challenge of making a conclusive diagnosis in some patients. The current

available technologies, MRI, CT and discography, often do not provide information to make a definitive diagnosis. Even though discography is used in the diagnosis of DDD in the lumbar spine by some, it remains controversial. 2.) The need for a clinical trial in the US to provide conclusive evidence about the health benefits provided from the fusion procedure for DDD in the lumbar spine. Additional discussion about the challenges of developing such a trial and some of the ethical issues took place. 3.) The lack of an available structured, rigorous, comprehensive non-operative rehab program to address low back pain for DDD in the US. 4.) The challenge of obtaining good data based on a coding system that is not specific enough to drill down to the diagnosis of DDD.

Open Panel Deliberations. The panel conducted discussion among themselves prior to voting.

Formal Remarks and Voting. The panel voted on Questions 1 through 6, with the results being recorded on individual tally sheets and compiled by staff. After the vote on each question, discussion was held among the panelists concerning each question voted upon, and addressing the discussion topics included with the questions. The final results of the voting are posted on the CMS web site. In general the panel determined that the evidence was weak in supporting that lumbar spinal fusion for DDD improves clinical outcomes as compared to conservative treatment. The results of the voting on each question were as follows:

All votes for the questions were on a scale of one to five, with one being the least favorable and five being most favorable.

Question 1: What level of confidence does the evidence provide in addressing the outcomes needed to determine the effectiveness of lumbar spinal fusion for low back pain

due to lumbar degenerative disc disease? The average score for the voting members of the committee was 2.89. The overall average for all committee members was 3.00.

Question 2: What level of confidence does the evidence provide for characterizing the complications, adverse events and other harms from lumbar spinal fusion for degenerative disc disease?

A. Short Term (up to 2 years post fusion surgery). The average score for the voting members of the committee was 2.33. The overall average for all committee members was 2.54.

B. Long Term (more than 2 years post fusion surgery). The average score for the voting members of the committee was 1.78. The overall average for all committee members was 1.85.

Question 3: Based on the evidence presented, how likely is it that lumbar spinal fusion for lumbar degenerative disc disease improves clinical outcomes as compared to conservative treatment?

A. Short Term (up to 2 years post fusion surgery). The average score for the voting members of the committee was 2.22. The overall average for all committee members was 2.46.

B. Long Term (more than 2 years post fusion surgery. The average score for the voting members of the committee was 1.50. The overall average for all committee members was 1.67.

Question 4: Based on the evidence presented, how likely is it that the various fusion procedures improve health outcomes for lumbar degenerative disc disease? Consider these procedures both with and without instrumentation.

A. Short Term (up to 2 years post fusion surgery)

Lumbar Fusion Procedure Without Instrumentation

a. Posterolateral (gutter fusion) - The average score for the voting members of the committee was 2.38. The overall average for all committee members was 2.38.

b. Posterior Lumbar Interbody/ Transforaminal Interbody - The average score for the voting members of the committee was 1.85. The overall average for all committee members was 1.85.

c. Anterior Lumbar Interbody - The average score for the voting members of the committee was 2.31. The overall average for all committee members was 2.31.

d. Anterior/Posterior combined - The average score for the voting members of the committee was 1.92. The overall average for all committee members was 1.92.

Lumbar Fusion Procedure/ With Instrumentation

a. Posterolateral (gutter fusion) - The average score for the voting members of the committee was 2.50. The overall average for all committee members was 2.50.

b. Posterior Lumbar Interbody/ Transforaminal Interbody - The average score for the voting members of the committee was 2.00. The overall average for all committee members was 2.00.

c. (formerly d) Anterior/Posterior combined - The average score for the voting members of the committee was 2.42. The overall average for all committee members was 2.42.

B. Long Term (more than 2 years post fusion surgery)

Lumbar Fusion Procedure Without Instrumentation

a. Posterolateral (gutter fusion) - The average score for the voting members of the committee was 1.85. The overall average for all committee members was 1.85.

b. Posterior Lumbar Interbody/ Transforaminal Interbody - The average score for the voting members of the committee was 1.77. The overall average for all committee members was 1.77.

c. Anterior Lumbar Interbody - The average score for the voting members of the committee was 2.00. The overall average for all committee members was 2.00.

d. Anterior/Posterior combined - The average score for the voting members of the committee was 1.69. The overall average for all committee members was 1.69.

Lumbar Fusion Procedure/ With Instrumentation

a. Posterolateral (gutter fusion) - The average score for the voting members of the committee was 1.82. The overall average for all committee members was 1.82.

b. Posterior Lumbar Interbody/ Transforaminal Interbody - The average score for the voting members of the committee was 1.67. The overall average for all committee members was 1.67.

c. (formerly d.) Anterior/Posterior combined - The average score for the voting members of the committee was 1.92. The overall average for all committee members was 1.92.

Question 5: What level of confidence does the evidence provide that radiographic interpretations are correlated with clinical outcomes for lumbar spinal fusion due to lumbar degenerative disc disease? The average score for the voting members of the committee was 1.54. The overall average for all committee members was 1.54.

Question 6: Based on the evidence presented, how likely is it that the results generalize to the Medicare population?

A. Relief of pain - The average score for the voting members of the committee was 2.85. The overall average for all committee members was 2.85.

B. Complications, adverse events and other harms - The average score for the voting members of the committee was 2.46. The overall average for all committee members was 2.46.

The results of the voting shows a need for better evidence to conclusively demonstrate the improvement in health outcomes from lumbar spinal fusion for low back pain due to degenerative disc disease.

Adjournment. The meeting adjourned at 3:09 p.m.

I certify that I attended the meeting
of the Medicare Coverage Advisory

Committee on November 30, 2006,
and that these minutes accurately
reflect what transpired.

Michelle L Atkinson

Michelle Atkinson
Executive Secretary, MCAC, CMS

I approve the minutes of this meeting
as recorded in this summary.

Alex H. Krist, M.D.
Chairperson