



**FINAL MEETING MINUTES
May 16, 2008**

Members Present: Ronald Bowman, M.D., Chair; Timothy Keenen, M.D., Vice-Chair; Hans Carlson, M.D.; Gary Rischitelli, M.D.; Brad Lorber, M.D.; John Braddock, M.D.; Tom Williams, P.T.; Maria Carraher, Injured Worker Rep and Joey Blubaugh

Members Absent: Franklin Wong, M.D.; Frank Prideaux, D.C and Pam DeVisser, F.N.P.

WCD Staff Present: Kevin Willingham; Jacqueline Sewart; Juerg Kunz; Denise Hunt; Nathan Johnson (IMD) and Donald Gallogly (IMD)

Welcome New Member(s):

New to the Workers' Compensation Division and to the Medical Advisory Committee is Jacqueline Sewart, Assistant Manager, in the WCD, Medical Section. Jacqueline will be taking Debra Buchanan's place on the committee. Another new member to the committee is Joey Blubaugh from TNT Management Resources. Both were introduced and welcomed by the committee members.

Approval of Prior Meeting Notes:

Due to the cancellation of the March 16, 2008 meeting, the minutes dated January 18, 2008 were reviewed by the committee members. A motion was made by Dr. Lorber and seconded by Dr. Braddock to approve the minutes as written.

Proposed Rule Hearing: *Juerg Kunz*

Lumbar Artificial Disc Replacement (ADR):

Juerg Kunz informed the committee that WCD has received one testimony, so far, in regards to these proposed rules. The actual hearing is scheduled for Monday May 19, 2008 and the last date to send in written testimony is May 22, 2008. It's a possibility that we could get additional testimony. The testimony WCD received was from DePuy Spine, Inc. (a Johnson & Johnson company). DePuy Spine would like the removal of the laminectomy from the absolute contra-indications. Dr. Lorber stated "The laminectomy issues were a matter of semantics. The reason the committee put this in there was because doing a true laminectomy involves the removal of the facet joints. The easiest way to clarify this is to say that any laminectomy that involves any part of the facet joints is an absolute contra-indication". The whole committee agreed with Dr. Lorber's statement. WCD will then submit testimony on behalf of the committee. WCD will contact Dr. Bowman if WCD receives additional testimony on lumbar ADR.

Fiscal Impact of Proposed Rule:

Juerg Kunz asked the committee if they have any in-put or ideas about any possible fiscal impact of the lumbar ADR decision. The way it stands currently, it is not excluded from compensability at all and no patient selection criteria is required. As part of WCD's statutory requirements for the rules process we have to try and anticipate the fiscal impact on the system.

Fiscal Impact of Proposed Rule Continued:

In this case, WCD did make a statement that says: The restrictions on the ADR could have a slight negative fiscal impact on surgeons who perform disc replacements. Those surgeons may perform other procedures on patients that do not meet the criteria for disc replacement. ADR is not a commonly used procedure so the overall fiscal impact should be small. Kevin Willingham asked the committee if they agreed with this statement. The committee then went into a discussion period and agreed with this minimal impact statement

Conversion Factors:

Kevin Willingham described the process on conversion factors from the beginning. In 2007 as part of the rules process we discovered the centers for Medicare/Medicaid services had adjusted the relative value units related to many of the evaluation/management category CPT codes. Had we done nothing, it would have amounted to a 14 million dollar projected increase in the workers' compensation medical system. To off set that we decreased the conversion factor. From our prospective we were just maintaining current levels not reacting to policy decisions that CMS had implemented. Not only did we get in-put at the time of the rules and testimony on the rules, we continued to get in-put from physicians across the state throughout the year. What we heard was E&M is too low. It is lower than what we're getting in private health and you're running the risk of losing physicians in the state because it's that low. We do have a policy direction given to us at this point to try to maintain cost neutrality in the system at least for now. We know we can't do that forever, but for now we will try to maintain neutrality in the system.

The other feedback we were getting was that the surgical conversion factor was higher than private health. So if something needed to be cut, cut surgery and give us some relief in evaluation and management. So we took the information and the in-put that we were getting from physicians back to see how we could accomplish that. We were looking at ways that we could increase the evaluation of management because the in-put we received stated E&M was the "bread and butter" codes and that's where we need it since all physicians and providers bill under E&M. We were looking for ways to accommodate what we were hearing from the public and still maintain this cost neutrality in the system. We looked at different levels of increasing E&M and what impact that would have on the surgical code. In doing that we arrived at proposing and recommending a \$5.00 increase in the E&M over the current 2007 level, but that would mean that a \$7.22 reduction in the surgical category. Based on the information we get from private health, this would still leave the surgical conversion factor higher than the private health conversion factor for surgery. We are limited in our data regarding conversion factors for private health. We have to trust what they give us. We know that is there generic conversion factor and we know that there are other things happening behind the scene that changes that. It is not transparent and it is not something that we get easily.

We also looked at the inflation factor and how does it factor into that. When we looked at total cost over time, even though the conversion factors had not changed much and we had maintained some cost neutrality within the system, the total medical costs were still rising. This signifies that there is still some inflation inherent in the system regardless of what our conversion factor is. Given all that information we had settled on the recommendation of increasing the E&M and decreasing the surgery. When we made that recommendation, our Information Management Division (IMD), our administrator asked the question, "Where are costs now in relationship to the ceilings for the conversion factors?". IMD did the best job they could in getting the information to us. IMD stated "It's dirty data, but the data overall shows system trends. You cannot rely on the absolute numbers, but you can rely on the trends". This is simply an attempt to try to address all of the interest in the system and still maintain access, maintain quality and make sure workers are getting the treatment they need. In Oregon we maintain a positive business climate so that employers can afford to purchase workers' compensation insurance.

Cervical Artificial Disc Replacement: *Dr. Keenen's presentation*

Dr. Keenen gave a visual presentation on cervical artificial disc replacement – medical issue review. The sub-committee members that reviewed the scientific literature were Dr. Keenen, Dr. Lorber, and Dr. Carlson. Dr. Keenen's presentation covered detailed information on the different device classifications, the exclusions and discussed what information was listed on the inclusions.

Devices:

In the cervical spine there is metal on plastic and metal on metal. The Prestige and the ProDisc C are the two cervical artificial discs that are FDA approved. The Bryan is pending FDA approval. Of these two that are FDA approved, the ProDisc C is a metal on polymer semi-constrained device and the Prestige is a metal on metal semi-constrained device. The Bryan is a metal on polymer semi-constrained device that is pending FDA approval and is close to being approved.

Differences:

The cervical artificial disc replacement is separate from lumbar in three primary ways:

First is surgical access. As spine approaches go, the anterior cervical approach used in cervical artificial disc replacement is a relatively simple and straight forward procedure. So the number of cases done will not be restricted because the surgeon requires help or a certain skill to get there. That's one of the reasons why the cervical artificial disc is different.

The second is the potential risk of the cervical artificial disc because one is working at the spinal cord level. The spinal cord is more sensitive to injury than is the cauda equina. The cauda equina is the nerves inside the spinal canal after the spinal cord ends. You are essentially dealing with peripheral nerves. Peripheral nerves can be moved and manipulated and still function; the spinal cord cannot.

Thirdly heterotopic ossification is unique to the cervical spine (it's not really spoken of much in the lumbar spine). Heterotopic (meaning – not where it's suppose to be) and ossification (meaning – the formation of bone). True heterotopic ossification may occur in someone who has been involved in a car accident or had a hip replacement and the muscle adjacent to the hip joint forms bone. There are reports mentioning heterotopic ossification, but we're not really talking about bone collecting in the muscles adjacent to the spine; we're talking about the bone where the implant is placed having a bridging bone. Early on in the cervical disc experience this heterotopic ossification was a significant issue. They put in the artificial discs, they got bridging bone, the discs didn't move so the patient essentially ended up with a fusion. In the learning curve of putting artificial discs in, this problem has largely gone away.

MRIs:

There are two metals used for artificial discs - titanium and cobalt chrome alloys. Both types of metals work just fine. There is really not an issue with whether they break, how long they last or how well they go in. Titanium allows you to get an MRI scan, cobalt/chrome does not. You can put somebody in an MRI scan with cobalt/chrome and they will not be at risk, but you cannot see anything. The cobalt/chrome alters the magnetic image so you get a big black spot and you cannot see the spinal cord. It does not hurt the patient, you just cannot get any information at that level. The same is true for lumbar and cervical.

Two devices - the Prestige and the Bryan are titanium. The ProDisc C is cobalt and chrome. In the long run the manufacturers of these companies will probably all go towards titanium for the simple reason that you can get an MRI scan.

Study Summary:

There are a smaller number of patients in randomized controlled trials and there are fewer studies than with lumbar artificial disc. Out of the 51 articles, most studies do not have enough patients or have a long enough follow up to be useful to us. Therefore, we are basically left with FDA approval studies¹ and they basically say that there is a similar risk and a similar degree of pain relief between the artificial discs (Prestige and ProDisc C) and fusion. In the Prestige study 11% of the study population were the workers' compensation patients and they seemed to do as well as non workers' compensation patients. The ProDisc C did not include workers' compensation patients.

Inclusion Criteria:

The inclusion criteria for cervical disc are either a disc herniation or degenerative disc disease with some combination of neck and arm pain lasting at least three months and having failed non-surgical treatment such as physical therapy and injections.

Exclusion Criteria:

Dr. Keenen, Dr. Lorber and Dr. Carlson reviewed all of the exclusion criteria that Juerg Kunz compiled from all of the studies and limited it to these:

- More than one cervical level
- Instability in the cervical spine which is greater than 3.5 mm of anterior motion or greater than 20 degrees of angulation
- Significantly abnormal facets
- Osteoporosis defined as T score greater than -2.5
- Allergy to the metal implant
- Bone disorders (any disease that effects the density of the bone)
- Uncontrolled diabetes mellitus
- Infection (local/systemic)
- Active malignancy (primary/metastatic)
- Bridging osteophytes (severe degenerative disease)
- A loss of disc height greater than 50%-75%

Presentation Discussion:

The committee went into a discussion period and discussed first whether cervical artificial disc replacement should be non-compensable based on whether it is experimental, unproven, unscientific or outmoded. The committee concluded and voted unanimously that cervical artificial disc replacement should be excluded from compensability unless it is:

- A semi-constrained metal on polymer device **or**
- A semi-constrained metal on metal device
- And (all of the following)
 - The patient is between 16 and 60 years old;
 - It is a single level disc replacement between C3 and C7;
 - The patient underwent unsuccessful conservative treatment; and
 - There is intraoperative visualization of the surgical implant level

The committee then went on discussing the exclusion criteria listed by the subcommittee. The committee added chronic indefinite corticosteroid use to the exclusion criteria list. The committee members agreed that the exclusion criteria listed are all absolute contraindications.

¹ FDA study for Prestige at 541 patients and the study for ProDisc C at 209

Presentation Discussion Continued:

Based on today's discussions and conclusions, WCD will prepare a document similar to the one created for the lumbar ADR as the basis for continued discussions regarding cervical artificial disc replacement.

Pharmacy:

Previous public policy established economic incentives for pharmacists to work with patients and doctors to move towards generic drugs rather than using name brand drugs, which has generated system savings. Under the new pharmacy fee schedule, Brand name and generic drugs are at the same reimbursement level. This maintains the incentive to move pharmacists to work with patients and doctors to dispense generic drugs more often.

Adjournment:

Meeting began at 9:00 a.m. and adjourned at approximately 11:30 a.m.

Next Meeting:

- July 18, 2008 from 9:00 - 11:30 a.m. at Clackamas Community College Training Center, Wilsonville

Recorder: Denise Hunt