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NEUROLOGICAL SURGEONS

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Josiah Morse, MPH  
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**Re: AANS/CNS Comments on Draft Technical Assessment for Washington State HTA Re-  
review of Lumbar Spinal Fusion**

Dear Mr. Morse:

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves, and the Washington State Association of Neurological Surgeons (WSANS), we appreciate the opportunity to provide comments regarding the draft evidence assessment prepared for the Washington State Healthcare Authority (WCA) Health Technology Assessment (HTA) program re-review of coverage policy for lumbar spinal fusion for degenerative disc disease (DDD). We have provided the following remarks based on our study of the draft report. We add these comments to those that we submitted in our letter May 20, 2015 regarding the draft Key Questions used for the report. We look forward to publication of the final report and to the discussion by the Health Technology Clinical Committee (HTCC) on November 20, 2015.

***Cited Literature Does Not Warrant a Policy Change***

The document prepared by the Institute for Clinical and Economic Review (ICER) is a thorough review of the literature. However, as we stated when the HTA program first suggested that the 2008 HTA Lumbar Fusion for DDD coverage policy be revisited, we do not believe that there is a substantial change in evidence for this procedure and we do not support a change to the current policy, which was based on significant stakeholder input and a robust review by the HTCC. Nevertheless, we would like to provide the following commentary on various aspects of the ICER report.

***Clarification that the Scope for the Report is for Uncomplicated DDD Only***

The key questions for the report are specific to the treatment of chronic low back pain and uncomplicated DDD. As such, the title of the draft report is slightly misleading as it gives the impression that it pertains to all lumbar fusions, and not the specific disease entity of chronic low back pain and uncomplicated DDD. ICER should clarify this in the title of the

final report. The focus of the HTCC meeting discussion should be limited to the specific topic of chronic low back pain and uncomplicated DDD.

### ***Heterogeneous Patient Population***

As is the case with any review of the literature, it is very difficult to find studies that precisely provide information on the desired subject matter, as the diagnosis of chronic low back pain and uncomplicated DDD might not apply to the subjects enrolled in the clinical trials for Key Question #1. Brox et al, Fritzell et al, and Fairbanks et al. all included patients with previous surgeries. The duration of symptoms in all of these studies was 8 years. Some of these patients with prior surgery who did not improve may have entered the trial with a diagnosis of failed back syndrome, and possible neuropathic symptoms. Average symptoms were present for 8 years. In the sport trial data, surgery was associated with significantly better outcomes when symptom duration was less than 12 months. (Radclif et al 2011, Spine (Phila Pa 1976). 2011 Dec 1; 36(25): 2197–2210. PMID: PMC3236684). In this sense, the studies used to answer Key Question # 1 might not completely reflect what the HTA program is attempting to study. It is possible that patients in these reported clinical trials may have benefitted to a greater extent from surgery if they were referred to spine surgeons at an earlier date.

### ***Limitations of Studies from Outside the United States***

Furthermore, the core studies used in the review have many well-known limitations as they are from outside the United States (US)—from the United Kingdom, Norway, and Sweden specifically. This introduces a serious population selection bias compared to our US and Washington state populations. Because these groups differ substantially to the US population, we do not feel that we can draw valid conclusions on how to manage our patients from this data. This issue was raised at the November 2007 HTCC meeting and it was clear that significant differences in culture and alternative treatments exist between the United States and Europe.

### ***Patient Safety Data***

Regarding the section on complications from spine surgery, it is important to note mention of Goz et al's study using the NIS data to evaluate three different primary interbody fusion cohorts (923,038 fusions) over nine years. In this study, patients with uncomplicated DDD represented a majority of patients for each fusion group. A recent article by Gologorski et al (J Neurosurg Spine. 2014 Dec;21(6):984-93. doi: 10.3171/2014.8.SPINE131113) demonstrates that primary ICD-9-CM codes extracted from large administrative databases (NIS in particular) do not accurately reflect the surgeon's indication. As such, we cannot extrapolate on complication rates of lumbar fusion using datasets that might not even correctly portray the patients with diagnosis of interest.

We feel that it would be important to include results from Level 1 data on the purest of LBP populations--artificial disk replacement versus fusion. Data from the fusion arm is not represented adequately in the ICER report. Including this data would provide valuable high quality context for important quality of life and function as well as safety data. In addition,

this data frequently comes from the US. We suggest the use of the Washington state Surgical Care Outcomes Assessment Programs (SCOAP) data base as a realistic patient safety assessment as it contains helpful real time data on complications. Furthermore it may be helpful to examine other high quality data registries such as the AANS/CNS National Neurosurgery Quality and Outcomes Database (N2QOD).

### ***Cost Effectiveness Data***

Incremental cost effectiveness of lumbar fusion when compared to non-operative treatments needs to be assessed on a long term basis. Numerous studies will demonstrate costly treatments in the fusion group. However, the true cost effectiveness of surgery is not realized until several years after fusion surgery. Further long term data will need to be collected to demonstrate long term cost effectiveness and long lasting effect of spine fusion despite the known risks of spine surgery. Andersen et al recently report that spinal fusion surgery in older patients does not generate excess hospital-based health care use in the longer term as compared with the background population.( Eur Spine J. 2013 May;22(5):977-84. doi: 10.1007/s00586-012-2479-5. Epub 2012 Aug 21. PMID: 22907726).

### ***Cognitive Based Therapy for Uncomplicated DDD***

We also feel that cognitive based therapy (CBT) is not a standard treatment alternative to fusion surgery. First of all, there is no clear definition to CBT. In addition, extreme selection bias exists with regard to which CBT therapy would apply to which patients. The Cochrane review concluded that CBT was useful for treatment of chronic pain , but different types of studies and analyses are needed to identify which components of CBT work for which type of patient on which outcomes and why (Williams, Cochrane 2012). Rather than asking if CBT or fusion is the better treatment modality, we really need to ask who needs either or both treatments and whether access to this kind of treatment specifically for uncomplicated DDD exists in the state of Washington or anywhere else in the US.

### ***Conclusion***

Thank you for your time and attention. We look forward to the November 20, 2015 meeting of the HTCC. We ask that a neurosurgeon with an active practice in spine surgery be included as the invited physician expert for the meeting and we can help identify appropriate neurosurgeons in the state of Washington to serve. As we have during our participation with the HCA HTA in the review of many neurosurgical procedures over the last eight years, we share the agency's dedication to the best possible healthcare for citizens of the state of Washington.

Sincerely,



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