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Re: AANS/CNS Comments on Key Questions for Washington State HTA Re-review of Lumbar Spinal Fusion Coverage Policy

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 Key Questions published by the Washington State Healthcare Authority (WCA) Health Technology Assessment (HTA) program for the technical assessment for the re-review of coverage policy for lumbar spinal fusion scheduled on November 20, 2015. We have provided the following comments to the Key Questions. We are aware that the draft technology assessment will be released on or about August 17, 2015, and we look forward to providing more in-depth comments upon its publication.

Key Question #1

What is the comparative clinical effectiveness of lumbar fusion surgery for patients with chronic low back pain and uncomplicated DDD relative to that of conservative management, minimally-invasive treatments, and selected alternative surgical approaches?

Studies on the comparative clinical effectiveness of lumbar spine fusion surgery relative to conservative management, minimally invasive treatments, and selected alternative approaches is limited. The existing literature demonstrates that both nonsurgical treatment and lumbar fusion surgery may improve function and pain for individuals with low back pain attributed to degenerative disc disease, however, limited evidence suggests that lumbar fusion may result in better outcomes compared to nonoperative treatment for certain individuals [1-4]. In 2014, the American Association of Neurological Surgeons and the Congress of Neurological Surgeons published a joint systematic review and reported a Grade B Recommendation to support lumbar fusion for patients with chronic low back pain that is refractory to traditional conservative treatment [5].

Key Question #2

What are the rates of “treatment success” or “successful clinical outcome” of lumbar fusion as defined by measures of clinically-meaningful improvement in pain, function, quality of life, patient satisfaction, and/or work status?

Currently, the primary treatment for most individuals with low back pain related to lumbar degenerative disease is nonoperative therapy. However for those with chronic disabling pain refractory to conservative measures, lumbar fusion surgery is a potential therapeutic option. In a select population, prospective studies demonstrate a 36.0 - 63.9% reduction in back disability as measured by the Oswestry Disability Index (ODI) at 2 years after lumbar fusion [1-4]. Back pain scores also decrease 31.9 - 54.6% over the same duration [1, 2, 4]. Further, lumbar fusion is associated with a 130.9 – 140.6% improvement in overall health as measured by the physical health component of the Medical Outcomes Study 36-item Short Form Health Survey (SF-36) [3].

To date, there are four multicenter randomized controlled trials comparing lumbar fusion surgery versus nonoperative treatment for low back pain attributed to degenerative disc disease. All four studies employed standardized patient-centered outcome measures to assess function and pain. The Swedish Lumbar Spine Study Group randomized patients who failed conservative therapy for ≥ 2 years to lumbar fusion surgery versus nonoperative therapy (ranging from physical therapy, education, transcutaneous electrical nerve stimulation, epidural steroid injections, cognitive and functional training, and/ or coping strategies) [6]. Patients were evaluated for 2 years post treatment. The surgical group demonstrated a 33% reduction in back pain score and a 25% decrease in ODI. Sixty-three percent of surgical patients rated themselves as “much better” postoperatively, and 36% had returned to work. Comparatively, the nonsurgical group demonstrated only a 7% reduction in back pain score and a 6% decrease in ODI. Only 29% of nonsurgical patients rated themselves as “much better” after treatment, and only 13% had returned to work.

Brox et al randomized patients with low back pain who had failed 1 year of conservative therapy to lumbar fusion versus a nonsurgical treatment protocol consisting of a 3 week program of physical therapy, cognitive intervention, education and peer counseling [7]. Patients were evaluated for 1 year post treatment. The surgical group demonstrated a 36.6% reduction in back pain score and a 37.1% decrease in ODI. Conversely, the nonoperative group demonstrated only a 24.0% reduction in back pain score and a 30.9% decrease in ODI. Overall, 71% of surgical patients rated their treatment as successful compared to 63% of nonoperative patients. In a similar study, Brox et al randomized patients with low back pain after prior disc herniation surgery to either of the same treatment arms [8]. More modest improvements were observed overall with the lumbar fusion group demonstrating a 21.5% reduction in back pain score and a 18.9% decrease in ODI. The nonsurgical group demonstrated a 23.5% reduction in back pain and a 28.4% decrease in ODI.

Fairbank et al randomized patients with degenerative disc disease related low back pain to lumbar fusion surgery versus nonoperative therapy consisting of an intensive rehabilitation program of cognitive behavioral therapy and exercise [9]. Patients were evaluated for 2 years post treatment. The surgical group demonstrated a 26.9% decrease in ODI compared to only a 19.4% decrease observed in the nonoperative group. Overall general health was assessed via the physical component of the SF-36, with the surgical group demonstrating a 148.5% improvement compared to only a 138.0% increase seen in the nonoperative group.

Key Question #3

What are the rates of adverse events and other potential harms (perioperative, long-term adverse events, and reoperations) associated with lumbar fusion surgery compared to alternative treatment approaches?

In several reported studies, lumbar fusion surgery for patients with chronic back pain related to degenerative disc disease with associated radiculopathy and dysfunction has been compared to disc arthroplasty, cognitive behavioral therapy, physical therapy and spinal injections. There is significant difficulty in comparing adverse events between these alternative treatments without defined endpoints. In 562 patients undergoing 1305 lumbar spinal injections over five years, there were 7.4% vascular penetration during injections as well 11.5% overall complications [10]. Inadvertent intradiscal injections during epidural and facet injections for degenerative disc disease contributing to back pain have been reported to be 2.3% [11]. This is a serious risk for further disc degeneration and also discitis. In the same study, risk of intravascular injection was 15.5% using fluoroscopy [11].

In reviewing the safety and efficacy of artificial disc replacement technologies for degenerative disc disease, there is evidence of up to 13% major complication rate [12]. Data from complications and adjacent level disc disease from lumbar disc arthroplasty for degenerative disease remain poor. There is underreporting of heterotopic ossification as well as implant extrusion into the abdominal cavity [12]. In the very robust study by the SWISS sine registry, reported major complications of 23.4% over 5 years with 248 patients. Also there was 13% ossification of treated segments as well as 11% adjacent level disease rate of which 50% of those patients requiring revision surgery [13].

Preoperative cognitive behavioral therapy and early rehabilitation have demonstrated reduction in disability only after surgical treatment of disease. They are more used to augment and reduce levels of catastrophizing and fear avoidance beliefs and less as an alternative to lumbar fusions for degenerative disc disease [14].

Early complication rates including adverse events are reported to be between 5 to 18% percent [7,15] for patient undergoing lumbar fusion for chronic back pain and disc degeneration with 1-3 level disease. This very well studied procedure includes predicted adjacent level disease rates requiring surgery at 10% over 10 years [16].

In summary, long term adverse events are not available for several of the alternatives to lumbar fusion therapy for chronic back pain related to degenerative disc disease above. Alternative therapies have been shown to lose effectiveness over time as well as incur significant risks to the patient.

Key Question #4

What is the differential effectiveness and safety of lumbar fusion according to factors such as age, sex, race or ethnicity, pre-existing conditions (e.g., smoking history), technical approach to fusion (e.g., posterolateral vs. interbody, minimally-invasive vs. open procedures), initial vs. repeat surgery, insurance status (e.g., worker's compensation vs. other), and treatment setting (e.g., inpatient vs. ambulatory surgery)?

While complication rates are higher in older patients, it is important to note that the elderly may still have good outcomes. A recent publication from the spine deformity study group (Smith et al.) comments on this topic [17]. In this paper, the authors reviewed 206 patients undergoing scoliosis surgery, and stratified them by age. While complications were significantly higher in the older patients, improvement in Oswestry disability index and leg pain were significantly greater among elderly patients ($P=0.001$). There were trends for greater improvements in SF-12 ($P = 0.07$), SRS-22 ($P = 0.048$), and back pain ($P = 0.06$) among elderly patients, when compared with younger patients. These data support the surgical treatment of elderly patients with scoliosis and suggest that the elderly, despite facing the greatest risk of complications, may gain a disproportionately greater improvement in disability and pain with surgery.

In 2007, Glassman et al. reported their clinical outcomes in patients over the age of 65 who underwent lumbar fusion. There was a mean improvement of 6.21 points in SF-36 Physical Composite Score and 5.75 points in SF-36 Mental Composite Score. There was a mean 16.38-point improvement in ODI, 3.08-point improvement in back pain, and 2.65-point improvement in leg pain. There was no difference in outcomes at 2 years postoperatively based on the occurrence of a perioperative complication. Hence confirming that despite an increase in complication rates in the elderly, outcomes themselves are not necessarily significantly influenced by these complications. The results of this study therefore support the efficacy of lumbar decompression and fusion in patients over 65 years of age, despite the known risk of complications in this patient population [18]

In 2015, Scuibba et al report better patient outcomes in patients with spinal deformity over the age of 75, when surgical intervention is pursued in comparison to non-surgical treatment. [19] In 27 patients, reconstructive surgery provided improved pain and disability scores over a 2-year period, with operative patients being more likely to reach minimum clinically important difference than non-operative patients.

When comparing minimally invasive fusions to standard open approaches, a recent meta-analysis from 2014 demonstrates relative clinical equipoise, and suggests that there is a need for higher quality studies to better assess this topic [20]. Nevertheless, it is well established the minimally invasive technique result in less blood loss and are associated with shorter hospital stays and as such, there are short term benefits, but long term benefits are questionable.

Regarding type of fusion performed, there is no conclusive evidence supporting better clinical or radiographic outcomes based on fusion technique. Therefore, when the AANS published their 2014 lumbar fusion guidelines, no general recommendation regarding superiority of one fusion type versus another was made [21].

Key Question #5

What are the costs and potential cost-effectiveness of lumbar fusion relative to alternative treatment approaches?

The 2014 AANS lumbar fusion guidelines evaluated recent literature regarding cost-effectiveness of Lumbar fusion [22]. The most important finding regarding cost effectiveness of fusion over other treatment modalities was that length of follow-up plays a large role in our ability to determine cost effectiveness. For example, an epidural steroid injection may control symptoms over a period of weeks, and is less expensive than a spinal fusion, but long term several epidural steroid injections per year will be more costly than a successful fusion.

Similarly, an anterior posterior lumbar fusion is more costly than a posterior only fusion. However, when evaluating long term outcomes, the more costly circumferential fusion (ALIF + posterolateral fusion) was found to be more cost-effective option than stand-alone posterolateral fusion at eight years [23].

There is Level I evidence to recommend either total lumbar disc replacement (TDR) or lumbar fusion from an economic perspective for the treatment of selected patients with chronic low back pain over a 2-year time period. One technique was not considered to be significantly superior [24]. From an economic perspective, both minimally invasive and open transforaminal lumbar interbody fusion techniques are equivalent options.

In 2007, the aggregate hospital cost for a primary diagnosis of lumbar stenosis was \$1.65 billion. According to a 2008 report, healthcare expenditures related to spine disease totaled \$86 billion in 2005. [25] These staggering sums underscore the importance of evaluating the potential cost-effectiveness of any intervention on the lumbar spine. However, the premise of this question would suggest that a thoughtful analysis of the current literature could provide the necessary evidence for a substantive answer regarding the cost effectiveness of lumbar fusion relative to alternative treatments. Such an analysis would require both a uniform definition of the clinical effectiveness of an intervention along with a well-defined fixed cost. In actuality, the literature regarding clinical effectiveness and cost is heterogeneous making the determination of cost-effectiveness inconsistent. Differences in cost have a direct effect on the value equation of whether an intervention is cost effective or not. The absence of a standardized methodology has therefore resulted in varied definitions of costs and cost effectiveness in the literature.

In its most elementary form, however, the true measure of cost-effectiveness is based on an individual's willingness to pay for a particular intervention with the expectation that such an intervention will improve their quality of life and decrease long term costs to manage their symptoms. By such criteria, it can be concluded that a single threshold for cost effectiveness does not exist. Even the literature is inconsistent with its definition of cost effectiveness with ranges from \$20,000/QALY to \$100,000/QALY. Due to the uncertainty of what defines true cost-effectiveness, investigators have constructed cost-effectiveness acceptability curves and have defined the minimum cost effective difference and minimal clinical important difference. While imperfect, it these studies that have demonstrated clinical benefit and cost effectiveness for the management of a variety of lumbar degenerative pathologies with lumbar fusion. The concept behind these curves demonstrate the probability that one intervention is cost-effective compared with another intervention given a maximum acceptable cost-effectiveness ratio (CER) by the decision maker. [26]

Acknowledging all of these shortcomings, there is still a large body of literature demonstrates the cost-effectiveness of lumbar fusion versus nonoperative measures. Fritzell and colleagues investigated fusion versus nonoperative treatment for chronic low-back pain and found significantly higher costs for fusion along with higher gains in quality of life in patients who underwent lumbar fusion. Despite this significantly higher cost, the authors concluded that lumbar fusion would be more cost-effective than nonoperative treatment due to the higher gains in quality of life [27]. Indrakanti and colleagues reviewed 27 articles that directly compared the cost benefit ratio of surgical intervention on the lumbar spine compared with nonoperative measures. Despite the heterogeneity of the data, these authors were able to conclude that operative care for treating spinal disorders involving nerve compression and instability were superior to nonoperative measures [28].

The final confounding factor is the complexity and heterogeneity of the degenerative pathologies of the spine. Almost all patients who undergo a surgical procedure have had some element of nonoperative measures prior to surgery. It is a consistent narrative that failure to find relief of symptoms with nonoperative measures ultimately leads patients to surgical intervention. Patients who elect to have nonoperative measures may not have a significant compromise in their quality of life to require surgery. Therefore, despite having the same diagnosis, these two patient groups may in fact represent two distinct entities: those who need surgery and those who do not. The relative cost effectiveness may not be one versus the other, but rather in parallel. This was well demonstrated in the Spine Patient Outcome Research Trial where a significant cross over rate from the nonoperative arm complicated the intention to treat analysis [29].

Thank you for your time and attention. We look forward to working closely with the agency during the re-review of lumbar spinal fusion coverage policy. We are eager to help identify neurosurgeon spine experts from the state of Washington and from our AASN/CNS Joint Section on Disorders of the

Spine and Peripheral Nerves to be involved in the effort. As we have during our participation with the HCA HTA in the review of many neurosurgical procedures over the last seven years, we share the agency's dedication to the best possible healthcare for citizens of the state of Washington.

Sincerely,



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Congress of Neurological Surgeons



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