March 21, 2018

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Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

SUBJECT: Washington State HTA Program Draft Evidence Report for Surgery for Symptomatic Lumbar Radiculopathy

Dear Mr. Morse:

On behalf of the American Academy of Orthopaedic Surgeons (AAOS), American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN), International Society for the Advancement of Spine Surgery (ISASS), North American Spine Society (NASS) and the Washington State Association of Neurological Surgeons (WSANS), we appreciate the opportunity to provide feedback on the draft evidence report related to surgery for symptomatic lumbar radiculopathy. Prepared by RTI International — Evidence-based Practice Center for consideration by the Washington State Health Care Authority (HCA) Health Technology Assessment (HTA) Program, we have concerns about this review and do not believe that the findings warrant any change in coverage for surgery for symptomatic lumbar radiculopathy.

Cited Literature Does Not Warrant a Policy Change

The draft evidence report represents a thorough review of the literature. Based on our analysis of the document and our interpretation of the literature, we do not believe that there is a substantial change in evidence on this topic and, therefore, we do not support a change to the current coverage policy. Surgery remains a cornerstone treatment option for patients with lumbar radiculopathy when considering both therapeutic value and cost-effectiveness. Our specific thoughts on this topic are listed below.

Limitations of Studies from Outside the United States

As we have asserted in previous comments to the HTA program, we are concerned about the inclusion of studies conducted outside of the United States. Other countries have significantly different health care systems, patient demographics and socioeconomics, and it is inappropriate to include these studies in this analysis. Despite repeated reservations about using the non-U.S. studies, a significant portion of the literature cited in the draft report comes from studies that conducted abroad. For example, of the 22 randomized controlled trials that were reviewed in Efficacy Question 1, only four were performed in the U.S. With such a high percentage of inapplicable literature as the basis of this draft report, we believe there may be a fundamental flaw in the conclusions drawn by the HTA, to the detriment of care for U.S. patients.

Compiling studies on cost-effectiveness from different healthcare systems is particularly vulnerable to error. Again, only two of the six studies included in the cost-effectiveness analysis were from the US. While the authors attempted to normalize cost through a conversion to 2010 U.S. dollars, this oversimplifies the

differences in economics and health care delivery across these very different systems. Data from national single payer systems and state-run health care programs are difficult to reconcile with the U.S. employer-based commercial payer system. Due to these differences, limiting the analysis to the studies from our country would have been more appropriate.

Long-term Outcomes of Operative vs. Nonoperative Management are Misrepresented

The draft evidence report concludes that compared to non-surgical management, surgery reduces pain and improves function up to 26 weeks of follow-up but the "difference does not persist at 1 year or longer." There is substantial high-quality literature that directly contradicts this statement regarding long-term outcomes. Results from the U.S.-based randomized-controlled Spine Patient Outcomes Research Trial (SPORT) are highly relevant to this discussion and underemphasized in the RTI-International prepared draft evidence report. In the SPORT trial, there was a high degree of crossover in the intent-to-treat analysis, which largely influenced the results and likely muted differences in outcomes between the groups. Despite the high crossover, there was still statistically significant improvement in secondary outcome measures favoring the surgical cohort at one year (sciatica bothersomeness index and self-rated improvement) and four years (sciatica bothersomeness index), which reflects improvement in patient quality of life. Furthermore, in the as-treated analysis, which likely better reflects true patient outcomes given the high crossover rate, treatment effects were statistically significant ***in favor of surgery*** for ***all*** primary and secondary outcome measures (with the exception of work status) at ***every*** time point, including the latest follow-up time point of four years.[1] These outcomes also persisted at the eight-year follow-up timepoint.[2] Results from this high-quality study conducted in the United States supports superior clinical outcomes for surgical treatment of lumbar radiculopathy compared with nonoperative management at long-term follow-up (8 years). There was a cursory mention of the limitation of ignoring "as-treated" analyses, but we believe this limitation deserves greater emphasis, particularly for this topic.

In the final analysis, the SPORT trial demonstrated benefit to patients who crossed over to surgery. That subset of patients would not have achieved or maintained the beneficial outcome without surgical intervention. Nor does the SPORT trial data support the contention that non-surgical management in persistently symptomatic patients with lumbar radiculopathy is equivalent to those patients who crossed over to surgery.

Minimally Invasive Surgery

Outcomes for minimally invasive approaches were comparable to more traditional open discectomy and microdiscectomy in the draft evidence report, and thus we support the continued use of minimally invasive approaches for this pathology, for appropriately selected patients. Literature confirms that minimally invasive techniques, such as endoscopic discectomy and tubular discectomy, may have distinct advantages — including shorter duration of operative time, less blood loss and shorter length of hospital stay — over more traditional approaches.[3-5] Additional research with high-quality, comparative studies is needed to better evaluate the clinical and economic value of these newer techniques. As technology continues to evolve, and surgical technique is refined, a greater benefit may ultimately be realized. Access to and application of new technology is critical to the evolution of surgical techniques and improvement in clinical outcomes, particularly in the case of less invasive approaches.

Inherent Limitations to Meta-analysis

While the draft evidence report represents an in-depth systematic review of the question at hand, it is also important to discuss the limitations of meta-analyses in general.[6] This study design is attractive due to the ability to dramatically increase study population size and assess treatment effect in a single large analysis. However, a variety of issues arise when attempting to combine these diverse studies into a single entity. A primary concern relates to patient heterogeneity. It is very difficult to maintain that all patients who are grouped together into one analysis represent the same patient population. Although significant overlap of

the inclusion/exclusion criteria exists for many of the studies cited, there are also distinct patient features in each study, which complicates the interpretation of this meta-analysis. For example, this applies to the diagnostic criteria being used for patient enrollment. As pointed out in the comment by Daniel Cher, MD, who is concerned about the potential misdiagnosis of sacroiliac (SI) joint pain as lumbar radiculopathy, the approach in ruling out SI joint pain as the primary pain source is variable across studies.

In addition, significant bias may be introduced when defining the inclusion/exclusion criteria for studies to be included in the meta-analysis. Many high-quality studies that do not meet the inclusion criteria of the draft evidence report would provide valuable insight into this topic; however, the results of these studies are not considered. Arbitrarily including randomized controlled trials (RCTs) from other countries but excluding observational studies from the U.S. may lead to potentially inappropriate assumptions on the relative importance of different components of study design. In summary, caution should be exercised in accepting the conclusions drawn by any meta-analysis, including those in the draft evidence report.

Conclusion

First and foremost, we note that our comments are intended to ensure continued access to optimal care for our patients. We are concerned that selective interpretation of the literature and the omission of essential other sources of scientific data could adversely affect such care and leave patients without access to the appropriate interventions. From a procedural standpoint, we ask that a neurosurgeon or orthopaedic surgeon with an active practice in spine surgery be included as the invited physician expert for the meeting and we would be pleased to help identify appropriate experts in the state of Washington to serve in this capacity. As we have demonstrated with our constructive engagement with the HCA HTA over the past decade, our societies share the agency's dedication to the best possible health care for citizens of the State of Washington.

Thank you for the opportunity to provide our comments. If you have any questions, or need additional information, please contact us.

Sincerely,

American Academy of Orthopaedic Surgeons
American Association of Neurological Surgeons
Congress of Neurological Surgeons
AANS/CNS Section on Disorders of the Spine and Peripheral Nerves
International Society for the Advancement of Spine Surgery
North American Spine Society
Washington State Association of Neurological Surgeons

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References:

1. Weinstein JN, Lurie JD, Tosteson TD, et al. Surgical versus nonoperative treatment for lumbar disc herniation: four-year results for the Spine Patient Outcomes Research Trial (SPORT). *Spine (Phila Pa 1976).* Dec 1 2008;33(25):2789-2800.

2. Lurie JD, Tosteson TD, Tosteson AN, et al. Surgical versus nonoperative treatment for lumbar disc herniation: eight-year results for the spine patient outcomes research trial. *Spine (Phila Pa 1976).* Jan 1 2014;39(1):3-16.
3. Dasenbrock HH, Juraschek SP, Schultz LR, et al. The efficacy of minimally invasive discectomy compared with open discectomy: a meta-analysis of prospective randomized controlled trials. *J Neurosurg Spine.* May 2012;16(5):452-462.
4. Clark AJ, Safaee MM, Khan NR, Brown MT, Foley KT. Tubular microdiscectomy: techniques, complication avoidance, and review of the literature. *Neurosurg Focus.* Aug 2017;43(2):E7.
5. Smith JS, Ogden AT, Shafizadeh S, Fessler RG. Clinical outcomes after microendoscopic discectomy for recurrent lumbar disc herniation. *J Spinal Disord Tech.* Feb 2010;23(1):30-34.
6. Eysenck HJ. Meta-analysis and its problems. *BMJ.* Sep 24 1994;309(6957):789-792.