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May 19, 2016

Josiah Morse, MPH, Program Director WA Health Technology Assessment Program Washington State Health Care Authority P.O. Box 4282 Olympia, WA 98504-2682 E-mail: shtap@hca.wa.gov

RE: Selection of Artificial Disc Replacement for Re-review by the Health Technology Assessment Program Health Technology Clinical Committee

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 on the Washington State Health Care Authority (HCA) Health Technology Assessment (HTA) plan to update its coverage policy for Artificial Disc Replacement.

We disagree that Cervical Artificial Disc Replacement should only be for reconstruction of single level discs. Two level cervical disc arthroplasty is well established in the literature and also is FDA approved. Please consider the most recent clinical trial results indicating significant advantages that two level artificial discs have versus 2 level cervical fusion. Davis et al in 2015 reported their 48 month follow-up data for a RCT on 2 level arthroplasty versus fusion. Patient outcome scores for satisfaction, NDI, SF-12 were all significantly higher for arthroplasty group. Re-operation rate was 4% versus 15% for arthroplasty versus ACDF. (1) Radcliff et al. in 2016 reported their 60 month follow-up data for a two level RCT. In this study, there was significantly higher satisfaction, NDI, and SF-12 scores in arthroplasty group, and reoperation rate significantly lower in arthroplasty group (4% versus 16%). (3)

We also disagree with committee conclusion that the comprehensive evidence review does not show that the technology is more cost effective. Various studies support the cost effectiveness of artificial discs. Radcliff in 2016 reported a statistically significant reduction in total costs paid by insurer in arthroplasty patients versus ACDF. Patients who underwent arthroplasty for single-level degenerative disease had lower readmission rates, lower reoperation rates, and reduced index and total costs than those treated with ACDF. Arthroplasty was effective in reducing the monthly cost of care compared with ACDF.(4) A five year comparison of artificial disc replacement to fusion demonstrated that ACDF and arthroplasty were both cost-effective strategies at 5 years, however arthroplasty was found to be the dominant treatment strategy in their analysis.(2)

Because two level cervical disk replacements have been FDA approved for several years, and because there is substantial scientific evidence to support its use with superior outcomes in comparison to fusion, we feel that the WA HCA needs to use more updated information in their assessment to provide adequate coverage to our patients.

Thank you for your time and attention to our comments. We look forward to providing further input as the issue is prepared for a meeting of the Health Technology Clinical Committee. As always, we urge you to include neurosurgeons in the assessment of the technology and as experts at the meeting. If we can provide any additional information at this time, please let us know.

Sincerely,

Frederich A. Bergs

Frederick A. Boop, MD, President American Association of Neurological Surgeons

Russell R. Lonser, President Congress of Neurological Surgeons

John J. Knightly, MD, Chairman AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves

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References

- 1. Davis RJ, Nunley PD, Kim KD, Hisey MS, Jackson RJ, Bae HW, Hoffman GA, Gaede SE, Danielson GO, 3rd, Gordon C, Stone MB: Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results. **J Neurosurg Spine** 22:15-25, 2015.
- 2. McAnany SJ, Overley S, Baird EO, Cho SK, Hecht AC, Zigler JE, Qureshi SA: The 5-year costeffectiveness of anterior cervical discectomy and fusion and cervical disc replacement: a Markov analysis. **Spine (Phila Pa 1976)** 39:1924-1933, 2014.
- 3. Radcliff K, Coric D, Albert T: Five-year clinical results of cervical total disc replacement compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled, multicenter investigational device exemption clinical trial. **J Neurosurg Spine**:1-12, 2016.
- 4. Radcliff K, Zigler J: Costs of cervical disc replacement versus anterior cervical discectomy and fusion for treatment of single-level cervical disc disease: an analysis of the Blue Health Intelligence database for acute and long-term costs and complications. **Spine (Phila Pa 1976)** 40:521-529, 2016.