



American
Association of
Neurological
Surgeons



CNS



INTERNATIONAL
SOCIETY for the ADVANCEMENT of
SPINE SURGERY



March 1, 2017

Josiah Morse, MPH, Program Director
Washington State Healthcare Authority
Health Technology Assessment Program
P.O. Box 42712
Olympia, WA 98504-2712

SUBJECT: Non-coverage Decision for Washington State HTA Re-review of Lumbar ADR: 20170120B.

Dear Mr. Morse:

We, the American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves, Washington State Association of Neurological Surgeons (WSANS), International Society for the Advancement of Spine Surgery and North American Spine Society (NASS), herewith express our resolute disagreement with the January 20, 2017, decision of the Washington State Healthcare Authority (HCA) Health Technology Assessment (HTA) program Health Technology Clinical Committee (HTCC) not to cover lumbar artificial disc replacement (ADR) surgery for all FDA approved indications. We concur with the decision to expand coverage to two level for cervical ADR as stated in the draft decision.

For the record, our combined societies express our concerns on behalf of our patients that we as medical professionals are entrusted to care for. Moreover, we are deeply concerned about the flawed process for re-review of the ADR lumbar policy, as well as the content of the draft findings and decision for ADR lumbar rendered by the HTCC on January 20, 2017. The member physicians of our professional societies wish it to be known that patients experiencing certain forms of severe life-altering low back pain, which has been shown to be refractory to all appropriate forms of nonoperative care, will be denied access to effective surgical treatment with the more recent January 20, 2017 decision. To be clear, we support the 2008 ADR lumbar decision, which permitted coverage under certain conditions following a period of nonoperative care. However, this recent decision is not compatible with the latest scientific evidence or reasonable methodology, nor does it reflect our professional experience of caring for our patients in the United States, nor was this re-review of lumbar disc replacement even necessary by the HTA/HTCC's own standards.

We believe the findings posted for ADR lumbar, as well as the process leading up to this decision, ignore sound fundamental scientific principles. The HTCC disregarded constructively rendered public comments voiced by true expert physicians in the field, the invited clinical panel expert and the

Director of the Washington State Surgical Care and Outcomes Assessment Program (SCOAP) for Spine, all of whom provided valid reasons not to change the ADR lumbar policy at this time.

Specific concerns with the non-coverage decision process

No need for re-review of ADR lumbar at this time

The call for a re-review of a previous HTCC decision should have been prompted by available ***new*** research data. The review of ADR cervical policy is appropriate, as new evidence strongly supports the safety and efficacy of additional level procedures. We commend the HTCC for this. However, the contracted review organization (CRO) failed to present any significant new studies that would support a change in the 2008 policy for ADR lumbar, or for that matter even a re-review.

Disregard for available registry data

Since the 2008 HTCC decision, several large-scale spine registries have become available. These provide high-quality prospective data. Due to its artificially narrowed allegedly scientific focus, the HTCC chose to ignore these data sources, including a Washington State spine surgery database (Spine SCOAP), which includes data from over 30,000 patients, prospectively captured, through hospital databases. With its self-imposed methodologic restrictions, the HTCC chose to ignore this valuable real-time safety data from its own state. The Director of the SCOAP program testified at the meeting that current analysis of data for ADR lumber shows strong safety and effectiveness with relatively low utilization and that the adverse events found in the European study do not appear to be of concern in Washington State.

Lack of Nonoperative Outcomes data

We continue to be concerned that the HTCC discusses nonoperative spine care without clear definitions or evidence that such care is available to patients in Washington State. The HTCC often uses phrases such as “intensive nonoperative care,” “cognitive behavioral back care,” “Structured, Intensive, Multi-disciplinary, Program (SIMP),” and similar terms in their discussions as modalities that are allegedly equivalent to surgery. Committee members did not attempt to define what such nonoperative care actually consists of, nor did they attempt to factually assess how many care facilities for some form of integrated multimodal nonoperative care programs actually are available to subscribers of HCA insurance products in Washington State — particularly in areas away from its major Western Washington urban centers. In reality, nonoperative care is expensive, frequently not available and usually not covered in the amount described in studies from Europe. The actual efficiency of nonoperative care – as nonstandardized as it is - very much remains in question.

As far as the AANS, CNS, WSANS and its observers were able to tell, the contracted review organization (CRO) and HTCC rested their findings mainly on a single PRCT from Norway. This study is flawed and not relevant to patient care in Washington State. Specifically the surgeons in this study did multilevel procedures in a third of patients – a procedure that is not FDA approved in the United States. In a third of patients, they did not utilize a general surgeon for access, which is a standard of care in the United States and they were not required to undergo formalized pre-training as is the case in our country. Sadly, the HTCC and its CRO ignored these important variables completely.

Moreover the lumbar ADR procedure numbers presented by the Director of Labor and Industries show a very low utilization rate and reflect a rare and prudent application of this device technology. Neither is there any discernible safety concern in Washington State, as presented by the Agency director, nor is there an abuse in procedure frequency.

Disregard of Professional Society Recommendations

Organized medicine takes its responsibilities for patients very seriously. This includes developing socially responsible management strategies for a wide variety of brain and spine conditions — including the management of chronic low back pain. We are disappointed that the HTCC and its CRO decided to brush aside the significant efforts of our professional neurosurgical societies, experts in the field of spine and high-quality published guidelines for the management of chronic low back pain. These efforts were undertaken according to the highest scientific standards, were discussed extensively in a discursive opinion forming process, and are published in the peer-reviewed literature. To ignore this scientific and clinical expertise, as well as that of the Washington State SCOAP Director, and the invited panel expert is very difficult to align with the statutory mission of the HCA and the HTCC.

Conclusion

In light of the above, the AANS, CNS, WSANS, ISASS and NASS, hereby request that the HTCC Decision **20170120B, Non-coverage for ADR Lumbar** be **suspended** for the following reasons:

- Lack of relevant new data to warrant re-review of this topic.
- Useful Data from the Washington State Spine SCOAP Registry is available now. Furthermore, more detailed data will soon be available and should be reviewed before a new policy is implemented for ADR lumbar spine. This data is likely much more useful for real time safety and utilization review and will offer more relevant insights than studies from other continents performed under artificial study premises.
- Flaws in the European study reviewed by the HTCC should be highlighted and the differences in practice, patient population and procedures should be thoroughly considered and weighed.
- In its present form, the HTCC decision is not credibly based on a fair and scientific process. In fact, it falls far short of this premise, thus calling into question its mission to provide appropriate health care to the patients under its purview.
- Lack of available appeals process for affected patients under the present HTCC decision process.

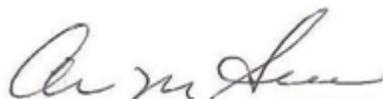
We are deeply concerned that the January 2017, HTCC decision not to cover ADR lumbar and the November 2015 decision not to cover lumbar fusion for patients with degenerative disc disease with low back pain, discriminate against injured workers and the poor in the state of Washington. These decisions subject many patients covered under the Washington State Health Care programs to only conservative therapy and opioid dependency without any chance of a surgical solution. Furthermore, we believe that the November 2015 non-coverage decision for lumbar fusion was inappropriately cited as a reason for non-coverage for ADR lumbar. We are also enclosing our letter regarding the November 2015 with this letter, as many of our concerns about the process are the same for both issues.

Thank you for the opportunity to provide our comments.

Sincerely,



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