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September 6, 2018

Daniel K. Resnick, MD, MS, President
North American Spine Society
7075 Veterans Blvd.
Burr Ridge, IL 60527

Via e-mail: coverage@spine.org

Subject: NASS Draft Coverage Policy for Lumbar Artificial Disc Replacement

Dear Dr. Resnick,

The American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS) and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN) appreciate the opportunity to provide comments on the North American Spine Society (NASS) coverage policy recommendations for Lumbar Artificial Disc Replacement. Below are our recommendations.

NASS Coverage Recommendations

1. *Lumbar Artificial Disc Replacement is indicated for patients with discogenic low back pain who meet ALL of the following criteria from the Lumbar Fusion Coverage Recommendation:*

Advanced single level disease noted on an MRI and plain radiographs of the lumbar spine at L4-5 or L5-S1, characterized by moderate to severe degeneration of the disc with Modic changes (defined as peridiscal bone signal above and below the disc space in question) as compared to other normal or mildly degenerative level (characterized by normal plain radiographic appearance and no or mild degeneration on MRI).

AANS/CNS/DSPN Comment on Modic Changes: After a review of the inclusion and exclusion criteria for the various IDE trials along with the Food and Drug Administration (FDA) approved indications and contraindications for lumbar arthroplasty devices, the AANS/CNS DSPN Payor Response Committee was unable to identify the evidence-based rationale for the coverage of an artificial disc in the lumbar spine being contingent on the presence of Modic changes of the segment in question. We agree that the current literature suggests that patients with Modic changes are candidates for lumbar arthroplasty. At the same time, there is ample literature that supports the fact that painful disc disease can exist in the absence of Modic changes. In the absence of instability, severe radiculopathy and the other listed exclusion criteria, lumbar arthroplasty should remain an option for these patients. Again, we are uncertain as to the evidence-based rationale to exclude patients from lumbar arthroplasty without Modic changes based on our review of the literature.

AANS/CNS/DSPN Comment on the levels of arthroplasty: The NASS Coverage Recommendations neglect to mention L3-4. The ProDisc-L is FDA approved for that level. We acknowledge that the activ-L IDE study reports only L4-5 and L5-S1, however, the NASS Coverage Recommendations should be device-neutral, regardless of the specific device used. We suggest that NASS broaden the inclusion criteria to cover L3-4 and believe that the coverage recommendations should at a minimum be consistent with the FDA labeling as indicated for each respective FDA approved disc.

2. *Presence of symptoms for at least 6 months or greater and that are not responsive to multi-modal nonoperative treatment over that period that should include physical therapy/rehabilitation program but may also include (but not limited to) pain management, injections, cognitive behavior therapy, and active exercise programs.*

AANS/CNS/DSPN Comment: We are in complete agreement with these inclusion criteria.

3. *Absence of poorly managed psychiatric disorders, such as major depression.*

AANS/CNS/DSPN Comment: The wording of “absence of poorly managed psychiatric disorders” is potentially confusing. Alternatives include, “Any underlying psychiatric disorder, such as depression, should be diagnosed and the management optimized prior to surgical intervention.”

4. *Lumbar Disc Arthroplasty is NOT indicated in ANY of the following scenarios:*

- a. *Any case that does not fulfill ALL of the above criteria.*

AANS/CNS/DSPN Comment: Again, we are concerned that these exclusion criteria mandate the presence of Modic changes for lumbar arthroplasty. As mentioned above, we have not been able to identify the evidence-based rationale. If the inclusion criterion above is modified, we would agree with this statement.

- b. *Presence of advanced multi-level degeneration (2 or more levels) on a preoperative MRI and plain radiographs.*

AANS/CNS/DSPN Comment: We are in large part in agreement with this comment but uncertain who determines the degree of degeneration. All of us have become familiar with the peer-to-peer process, where the reviewer makes a decision based on the radiology report. We suggest consideration of the development of criteria to determine the presence or absence of multi-level degeneration.

Concluding Thoughts

The AANS, CNS and DSPN appreciate the opportunity to comment on the NASS Draft Coverage Policy for Lumbar Artificial Disc Replacement and urge you to amend the document per our recommendations. In the meantime, please note that the views expressed in this letter are not an endorsement of any product mentioned in this correspondence, nor does this represent an endorsement of the coverage recommendations made by NASS.

Thank you for considering our comments. If you have any questions, or need additional information or clarifications, please feel free to contact us.

Daniel K. Resnick, MD, MS
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for Lumbar Artificial Disc Replacement
September 6, 2018
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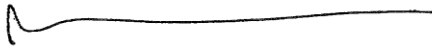
Sincerely,



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American Association of Neurological Surgeons



Ashwini D. Sharan, MD, President
Congress of Neurological Surgeons



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AANS/CNS Disorders of the Spine and Peripheral Nerves

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