

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS

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May 13, 2016

Tamara Syrek Jensen, JD, Director
Coverage and Analysis Group
Centers for Medicare & Medicaid Services
Office of Clinical Standards and Quality
7500 Security Blvd.
Mailstop S3-02-01
Baltimore, MD 21244

Re: National Coverage Analysis (NCA) for Percutaneous Image-guided Lumbar Decompression for Lumbar Spinal Stenosis (CAG-00433R)

Dear Ms. Jensen,

On behalf of the American Association of Neurological Surgeons (AANS), the Congress of Neurological Surgeons (CNS), and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves, we appreciate the opportunity to comment on the recent request for reconsideration of the National Coverage Analysis (NCA) for Percutaneous Image-Guided Lumbar Decompression (PILD) for Lumbar Spinal Stenosis (LSS).

We have reviewed the six month study data cited for the reconsideration and we do not believe it supports a change in the CMS decision of January 2014, covering the procedure only for approved clinical trials. We will be interested to see the full twelve months of data and until that time, do not support a change in coverage policy for the device. Although some neurosurgeons have been trained in the technique of percutaneous image-guided lumbar decompression (PILD) for the treatment of symptomatic Lumbar Spinal Stenosis (LSS), overall our field of neurosurgery has not embraced the use of this procedure due to concerns regarding its effectiveness as compared to our current surgical options. The literature continues to be predominantly industry funded and we continue to have concerns that the technique is not indicated in patients with a significant element of bony stenosis, lateral recess stenosis, or foraminal stenosis. While the literature suggests that the PILD procedure appears relatively safe, the improvements in the patients in previous studies did not meet a minimally acceptable outcome based on the definitions. We continue to have concerns about the characteristics of patients who would benefit from this procedure and the degree to which these patients would benefit as compared to current treatment options. We believe that CMS should wait for the full 12 months of data before reconsidering its non-coverage policy for this procedure.

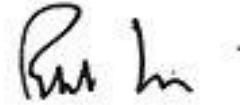
Thank you for the opportunity to comment. We look forward to seeing the full 12 months of data that CMS had requested two years ago when reaching the conclusion that the procedure should not be

covered outside of approved clinical trials. We concurred with the CMS conclusion at that time and have not yet seen evidence to support a change.

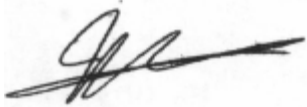
Sincerely,



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
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