



November 11, 2013

Via Email: CAGInquiries@cms.hhs.gov

Centers for Medicare and Medicaid Services
7500 Security Blvd.
Baltimore, MD, 21244

Re: CAG-00433N: Percutaneous Image-Guided Lumbar Decompression for Lumbar Spinal Stenosis

To Whom It May Concern:

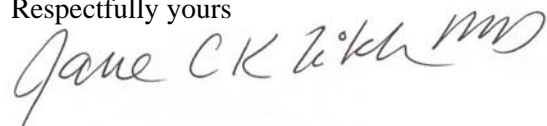
The American Society of Anesthesiologists (ASA) appreciates the opportunity to comment on the Center for Medicare and Medicaid Services (CMS) proposed decision to consider percutaneous image-guide lumbar decompression a non-covered procedure for the treatment of lumbar spinal stenosis. We urge CMS to refrain from finalizing a non-coverage decision at this time.

As noted in the proposed decision memo, the core question is, *“Is the evidence sufficient to conclude that PILD improves health outcomes in Medicare beneficiaries with lumbar spinal stenosis?”* CMS reviewed a great deal of information and literature - most of which indicated that the answer to that core question could be yes. Comments received in response to CMS’s initial analysis supported coverage. However, in this proposed decision, CMS takes a different view because it believes the studies leave some important questions unanswered. These include, lack of consensus on diagnostic criteria, lack of consensus on the treatment of LSS, and specifically on PILD as a form of treatment. CMS also expresses some concerns about industry financial support for some of the studies.

A non-coverage decision at this time is premature and could deny care and relief to patients who may benefit from the procedure. We understand that PILD is not necessarily appropriate for all patients with LSS and that there must be clear guidelines in place to determine patient selection for this procedure. We ask that CMS allow opportunity for interested stakeholders to address the concerns raised in the decision memo so that the core question can be fully considered and definitively answered.

Thank you for consideration of our comments,

Respectfully yours



Jane CK Fitch, M.D.

President

American Society of Anesthesiologists