September 6, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1656-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: Comments to CMS-1656-P (Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; etc.)

Dear Acting Administrator Slavitt:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), I am writing to submit comments in response to CMS-1656-P.

ISASS is a global, scientific, and educational society of spinal surgeons and scientists organized to provide an independent venue to discuss and address the issues involved with surgical aspects of the basic and clinical science of spinal care. Thank you for the opportunity to provide comments on the proposed rule.

On a broad level, ISASS believes that the surgeon, in consultation with the patient, is best equipped to determine the most appropriate site of service for surgical spine procedures after a thorough review of the patient's diagnosis, surgical plan, history, risk factors, and comorbidities. Simply because a procedure is listed by CMS as an ASC covered surgical procedure does not mean every case will be performed in the

ASC setting. The surgeon has the expertise required to determine which setting is most appropriate for each patient. We do not feel it is necessary for CMS to maintain separate lists for inpatient, outpatient, and ASC covered procedures, however, since CMS maintains this structure for facility payments, our comments below are tailored to this framework.

Changes to the Inpatient-Only List

ISASS supports CMS' proposal to remove the following spine codes from the inpatient-only list:

- CPT code 22840 - Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)
- CPT code 22842 - Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure)
- CPT code 22845 - Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)
- CPT code 22858 - Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)

ISASS supports this proposal and agrees with CMS that these are add-on codes to procedures that are currently performed in the hospital outpatient department and describe variations of the base code procedure, and therefore satisfy criterion three as they relate to codes that have already been removed from the inpatient-only list. While we appreciate the CMS' proposal to remove these codes from the inpatient-only list, CMS proposes to package all of the codes so that no separate payment is available. Although all of these codes are add-on codes to the primary procedure, they do significantly increase the cost of performing the procedure due to increased time in the operating room, increased staff time, additional supplies, and the cost of the implanted device. CMS should allow for separate payment of these codes to account for the increased procedure costs.

Proposed Additions to the List of ASC Covered Surgical Procedures

ISASS supports CMS' proposal to add the following spine codes to the list of ASC covered surgical procedures:

- CPT code 20936 - Autograft for spine surgery only (includes harvesting the graft); local (eg, ribs, spinous process, or laminar fragments) obtained from the same incision (List separately in addition to code for primary procedure)
- CPT code 20937 - Autograft for spine surgery only (includes harvesting the graft); morselized (through separate skin or fascial incision) (List separately in addition to code for primary procedure)

- CPT code 20938 - Autograft for spine surgery only (includes harvesting the graft); structural, biocortical or tricortical (through separate skin fascial incision) (List separately in addition to code for primary procedure)
- CPT code 22552 - Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical C2, each additional interspace (List separately in addition to code for separate procedure)
- CPT code 22840 - Posterior non-segmental instrumentation (eg, Harrington rod technique, pedicle fixation across 1 interspace, atlantoaxial transarticular screw fixation, sublaminar wiring at C1, facet screw fixation) (List separately in addition to code for primary procedure)
- CPT code 22842 - Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 3 to 6 vertebral segments (List separately in addition to code for primary procedure)
- CPT code 22845 - Anterior instrumentation; 2 to 3 vertebral segments (List separately in addition to code for primary procedure)
- CPT code 22851 – Application of intervertebral biomechanical device(s) (eg, synthetic cage(s), methlmethacrylate) to vertebral defect or interspace (List separately in addition to code for primary procedure)

ISASS strongly supports the addition of these codes to the list of ASC covered surgical procedures and commends CMS for recognizing the instrumentation codes, which are integral to fusions, as appropriate for the ASC setting. We agree with CMS that these procedures do not pose a significant risk to beneficiary safety when performed in an ASC and would not be expected to require active medical monitoring and overnight care of the beneficiary following the procedure. ISASS would like to point out that none of the 2017 proposed additions to the list of ASC covered surgical procedures are listed in the addenda spreadsheet; we believe this was an oversight on the part of CMS.

While we appreciate the CMS' proposal to add these codes to the list of ASC covered surgical procedures, CMS proposes to package all of the codes so that no separate payment is available. Although all of these codes are add-on codes to the primary procedure, they do significantly increase the cost of performing the procedure due to increased time in the operating room, increased staff time, additional supplies, and the cost of the implanted device. CMS should allow for separate payment of these codes to account for the increased procedure costs.

Effective January 1, 2017, CPT code 22851 will be deleted and replaced with the following three codes to report insertion of biomechanical spine devices:

- CPT code 22X81 – Insertion of interbody biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges) when performed to intervertebral disc space in conjunction with interbody arthrodesis, each interspace
- CPT code 22X82 – Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh) with integral anterior instrumentation for device anchoring (eg, screws, flanges) when performed to vertebral corpectomy(ies) (vertebral body resection, partial or complete) defect, in conjunction with interbody arthrodesis, each contiguous defect

- CPT code 22X83 - Insertion of intervertebral biomechanical device(s) (eg, synthetic cage, mesh, methylmethacrylate) to intervertebral disc space or vertebral body defect without interbody arthrodesis, each contiguous defect

If CMS deems CPT code 22851 appropriate for coverage in the ASC setting, then its replacement codes (CPT codes 22X81, 22X82, and 22X83) should also be added to the list of ASC covered surgical procedures as these codes will be used to report insertion of the same devices now reported using CPT code 22851, only with a greater level of specificity.

In addition to the codes listed above, ISASS suggests adding the following CPT codes to the ASC list of covered surgical procedures:

- CPT code 22856 - Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical
- CPT code 22858 - Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)

CPT code 22856, one-level cervical total disc arthroplasty ("cTDA"), was removed from the inpatient-only list effective January 1, 2013 and CMS proposes to remove CPT code 22858, two-level cTDA, from the inpatient-only list effective January 1, 2017. One-level cTDA is clinically similar to one-level anterior cervical discectomy and fusion ("ACDF") (CPT code 22551 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2)), which has been on the ASC list of covered surgical procedures since January 1, 2015. Two-level cTDA is clinically similar to two-level ACDF (CPT code 22552 (Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for separate procedure)) which CMS proposes to add to the ASC list of covered surgical procedures as part of the 2017 proposed rule. Many aspects of ACDF and cTDA are clinically similar including:

- Accessing the cervical spine using an anterior approach
- Performing discectomy, spinal cord and root decompression
- Preparing the end plates for device insertion
- Inserting a device/tissue into the interspace
    - For CPT codes 22551 and 22552, a cage (CPT code 22851), machine-prepared allograft dowel or structural allograft (CPT code 20931), or tri-cortical iliac crest autograft (CPT code 20938) is inserted into the interspace
    - For 22856 and 22858, a cervical artificial disc is inserted into the interspace

In addition, data from two published randomized control trials[1,2] comparing one- and two-level cTDA to ACDF show similar or better outcomes for one- and two-level cTDA performed in the

[1] Hisey MS, Bae HW, Davis RJ, Gaede S, et al. Prospective, randomized comparison of cervical total disk replacement versus anterior cervical fusion – results at 48 months follow-up. J Spinal Disorders Techniques 2015;28(4):e237-e243.

outpatient setting (i.e. surgery time, blood loss, return to work, perioperative adverse events, and subsequent surgery during the 90-day post-operative window). Proper patient selection is key to ensuring positive outcomes in the ASC setting. ISASS believes that similar to one- and two-level ACDF, and one- and two-level cTDA do not pose a significant risk to patient safety when performed in an ASC for properly selected Medicare beneficiaries.

ISASS appreciates the opportunity to comment on the proposed rule. Thank you for your time and for your consideration of our comments. Please contact Liz Vogt, Director of Health Policy & Advocacy by email at liz@isass.org or by phone at (630) 375-1432 with questions or requests for additional information.

Sincerely,

Morgan P. Lorio, MD, FACS
Chair, Coding and Reimbursement Task Force
International Society for the Advancement of Spine Surgery

[2] Davis RJ, Nunley PD, Kim KD, et al. 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 2015;22:15-25.