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Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1678-P  
P.O. Box 8013  
Baltimore, MD 21244-1850

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**RE: Comments to CMS-1678-P (Medicare Program: Hospital  
Outpatient Prospective Payment and Ambulatory Surgical Center  
Payment Systems and Quality Reporting Programs)**

Dear Administrator Verma:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), I am writing to submit comments in response to CMS-1678-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 the basic and clinical science of surgical spine 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 removed from the inpatient-only list or added to the ASC-covered list does not mean every case will be performed in the outpatient or 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.

### **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 22856** - Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy 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 osteophylectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (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. 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.

CPT code 22856, one-level cervical total disc arthroplasty ("cTDA"), was removed from the inpatient-only list effective January 1, 2013 and CPT code 22858, two-level cTDA, was removed 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, osteophylectomy 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, osteophylectomy 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 added to the ASC list of covered surgical procedures effective January 1, 2017. 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, machine-prepared allograft dowel or structural allograft, or tri-cortical iliac crest autograft 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<sup>1,2</sup> comparing one- and two-level cTDA to ACDF show similar or better outcomes for one- and two-level cTDA performed in the

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<sup>1</sup> 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.

### **ASC Quality Reporting Program**

CMS is proposing to adopt a new ASC quality measure, ASC-17: Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures, for the 2022 payment determination and subsequent years. The measure outcome is all-cause, unplanned hospital visits within seven days of an orthopedic procedure performed at an ASC. For the purposes of this measure, “hospital visits” include emergency department visits, observation stays, and unplanned inpatient admissions.

While we understand CMS’ interest in measuring unplanned hospital visits following an orthopedic procedure performed in an ASC, we believe that the proposed measure would generate more useful data if it were more narrowly focused. Rather than finalizing an all-cause hospital visit measure, CMS should instead adopt a measure that captures hospital visits directly tied to complications arising from the orthopedic procedure performed in an ASC.

ISASS appreciates the opportunity to comment on the proposed rule. Thank you for your time and consideration of our comments. Please contact Liz Vogt, Director of Health Policy & Advocacy by email at [liz@isass.org](mailto: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

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<sup>2</sup> 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.