February 18, 2016

Robert McDonough, MD
Head of Clinical Policy, Research and Development
Aetna Clinical Policy Unit
Aetna, Inc.
1000 Middle Street, MC17
Middletown, CT 06457

RE: Coverage Policy for Intervertebral Body Fusion Devices

Dear Dr. McDonough:

On behalf of the International Society for the Advancement of Spine Surgery (ISASS), I am writing to share our Society's concerns with your coverage policy for intervertebral body fusion devices, specifically related to cages for cervical fusion.

ISASS is a global, scientific and educational society organized to provide an independent venue to discuss and address the issues involved with all aspects of basic and clinical science of motion preservation, stabilization, innovative technologies, MIS procedures, biologics and other fundamental topics to restore and improve motion and function of the spine.

ISASS is concerned with Section IX - Intervertebral Body Fusion Devices (Spine Cages) of Aetna Back Pain – Invasive Procedures Policy Number 0016 ("Policy"). Section IX of the Policy allows coverage of cages for cervical fusion under the following indications:

A. Multilevel (three or more vertebral bodies) corpectomy (removal of half or more of vertebral body, not mere removal of osteophytes and minor decompression) in the treatment of one of the following:

1. for tumors involving one or more vertebrae, *or*
2. greater than 50 percent compression fracture of vertebrae, *or*
3. retropulsed bone fragments, *or*
4. central canal stenosis with myelopathy.

B. Multilevel (three or more vertebral bodies) fusion for pseudarthrosis in persons with prior fusion; *or*

C. For adjacent level disease that has developed in persons with a prior cervical fusion involving a plate, in order to avoid dissection for plate removal; *or*

D. Multilevel (three or more discs) discectomy in persons meeting criteria for cervical discectomy in CPB 0743 – Spinal Surgery: Laminectomy and Fusion; *or*

E. Jehovah's Witnesses with poor bone stock (e.g., due to osteoporosis, osteogenesis imperfecta, ESRD, diabetes, long-term steroid use, immunosuppression after transplant, or parathyroid deficiency).

Section IX of the Policy then states, "spine cages are considered experimental and investigational for all other indications because their effectiveness for indications other than those listed above has not been established." The Policy only allows coverage of cervical cages to avoid a more extensive surgery requiring plate removal at an adjacent level or for multi-level use; however, to our knowledge, there is not a cervical cage on the market approved for multi-level use. Cervical cages that have obtained FDA approval or clearance are for one or two level only, which means that the Policy allows for coverage of cervical cages in a manner inconsistent with the approved use of the device.

In order to avoid issues inherent to autograft and allograft, many surgeons rely on cages to provide stability, maximize fusion, reduce subsidence and structural failure and improve patient outcomes. When developing the surgical plan, the surgeon considers the needs of the patient along with his/her training, skill set and comfort level with different methods of achieving fusion. This Policy removes decision-making from the surgeon and introduces additional risk into the procedure by dictating a particular method for fusion. Requiring surgeons to use allograft rather than cages alters surgeon best practice and puts the patient at risk for increased complications and poorer outcomes. This is not acceptable and neither patients nor surgeons should shoulder the consequences of this shortsighted Policy.

Additionally, the appendix to the Policy contains lists (not all-inclusive) of covered and non-covered cages. ISASS is unclear as to why such lists are necessary to include in the Policy. All of the devices listed have been approved or cleared for use by the FDA. The surgeon evaluates the patient and performs the surgery and should have access to all available tools to effectively treat the patient. The surgeon is the only one with the knowledge and expertise necessary to determine the best method of achieving fusion for a particular patient, including whether a cage is necessary and the specific type of cage required. Payers should maintain focus on the medical necessity of procedures rather than developing and continually updating lists of covered and non-covered devices. ISASS does not endorse any specific device; there are

numerous cages that have received FDA 510 (k) clearance for use in cervical fusions. ISASS maintains that the surgeon, not the insurance company, should decide the type of device utilized in fusion procedures.

For your reference, I have attached the ISASS Cervical Interbody Policy Statement, which provides valuable history on the evolution of anterior cervical discectomy and fusion (ACDF) surgery, including the use of cervical cages to achieve fusion. New technology plays a vital role in the advancement of spine surgery as a whole and as a result, we continue to see fewer inpatient surgeries, shorter operating times, faster recovery times and increased patient satisfaction and quality of life. ISASS believes that the current policy restricts the use of cervical cages to the point of negatively impacting patient care. We advocate strongly for Aetna to support coverage of this treatment option based on documented medical necessity and indications for use set forth by the rigorous FDA processes.

ISASS values the partnerships established with our payer community and would welcome the opportunity to meet with members of your policy committee to discuss this issue further. Please do not hesitate to contact Liz Vogt, Director of Health Policy & Advocacy by email at liz@isass.org or by phone at (630) 375-1432.

We look forward to establishing a continued partnership with Aetna, so together we can advocate for quality patient care and superior patient outcomes.

Sincerely,

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

Enclosure:
ISASS Policy Statement – Cervical Interbody