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Robert McDonough MD
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Via e-mail: mcdonoughr@aetna.com

Subject: Aetna Medical Policy 0016 Section IX, E, Lumbar interbody fusions with expandable cages

Dear Dr. McDonough,

Over the last several months, spine surgeons across the country have received denial notices for the use of expandable interbody cages in lumbar interbody fusion procedures for patients covered by Aetna, as a result of the above-mentioned policy that considers expandable interbody devices to be investigational. The American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS) and the AANS/CNS Joint Section on Disorders of Spine and Peripheral Nerves (DSPN) strongly disagree with this characterization and appreciate the opportunity to present our analysis of the current literature regarding expandable interbody devices.

Aetna's current medical policy (0016, section IX, E) on expandable cages is below:

> "Expandable cages are considered medically necessary for persons who meet criteria for fusion in CPB 0743 – Spinal Surgery: Laminectomy and Fusion, and who meet either of the following criteria: 1) At L5-S1, where disc morphology is hard to reconstruct using standard static cages; or 2) for persons with osseous defects at the fusion site (i.e. voids or gaps in bone due to trauma, surgical resection or congenital defects). Expandable cages are considered experimental and investigational for all other indications."[1]

In 2015, the FDA approved the Elevate™ interbody device, manufactured by Medtronic Sofamor Danek, and it has since been used successfully in tens of thousands of cases nationwide. Although Aetna's policy limits the use of expandable cages to L5/S1, the Elevate™ device is indicated for interbody fusions at one or contiguous levels from L2-S1 in patients with degenerative disc disease or spondylolisthesis. Included is a copy of the implant information from the manufacturer for hospital/new technology committees.[3]

Expandable cages are particularly useful for collapsed disc spaces. Their lower profile facilitates insertion and allows for less nerve root retraction and decreases the potential of dural laceration. Several studies have shown that expandable cages allow for better restoration in disc and foraminal

height over static cages and may lead to better implant-bone opposition which promotes bony arthrodesis under principles set forth by Wolff's law.[4-7]

Hawasli et al. demonstrated that those patients with collapsed disc height using an expandable interbody device (via minimally invasive transforaminal technique) had superior and longer duration maintenance of increased disc space height, foraminal height, and index-level segmental lordosis compared to static interbody cages.[5] Additionally, expandable devices led to improved clinical outcome including Oswestry Disability Index (ODI) scores compared to static devices, especially in patients with pre-operative collapsed disc space.[5] Massie et al. noted that expandable interbody cages provided a significant restoration of segmental height, segmental lordosis and spinopelvic parameters, while leading to significant reductions in pain and disability.[7] Kim et al. reported significant improvement in clinical and radiographic outcomes using expandable cages, specifically reestablishment of disc height (8.3 +/- 2.7mm versus 11.3 +/- 1.9 mm), and higher fusion rates at 24 months than with static devices in a series of 50 patients.[6] The authors also note lower risks of implant migration, subsidence, breakage, and collapse by 12 months.[6] Alimi et al. discovered that expandable polyetheretherketone (PEEK) spacers can restore disc and foraminal height and improve patient outcomes without significant subsidence in 49 patients.[4]

Aetna's current policy is not consistent with the available literature as none of the studies limited expandable interbody devices to L5-S1. Aetna's limitation to the L5-S1 segment seems arbitrary with no supporting data from the literature. Similarly, the FDA approval does not limit the indications for use to a specific level.[2] Additionally, no other major insurer has a policy that considers expandable cages "experimental and investigational." It is difficult to reconcile how the use of an expandable interbody device is medically appropriate in one lumbar segment, but the same implant becomes experimental and investigational at another lumbar segment.

We are eager to understand Aetna's rationale, as we believe that Aetna's policy is limiting our patients' access to the highest quality care. For this reason, we strongly recommend that Aetna change its coverage policy to reflect the best available literature for lumbar interbody fusions with expandable cages. Our clinical and coding experts would welcome an opportunity to have a conference call regarding this matter with members of your coverage policy team, and Catherine Hill on our staff can help with these arrangements.

Thank you for considering our request. We look forward to hearing from you soon.

Sincerely,

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American Association of Neurological Surgeons

Ashwini D. Sharan, MD, President
Congress of Neurological Surgeons

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