AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS

KATHLEEN T. CRAIG, CEO 5550 Meadowbrook Drive Rolling Meadows, IL 60008 Phone: 888-566-AANS Fax: 847-378-0600 info@aans.org





CONGRESS OF NEUROLOGICAL SURGEONS

REGINA SHUPAK, CEO 10 North Martingale Road, Suite 190 Schaumburg, IL 60173 Phone: 877-517-1CNS FAX: 847-240-0804 info@cns.org

> President ELAD I. LEVY, MD Buffalo, New York

President ANTHONY L. ASHER, MD Charlotte, North Carolina

August 30, 2023

Brian Kane
Executive Vice President and President
Aetna
151 Farmington Avenue
Hartford, CT 06156

Robert McDonough, MD Senior Director, Clinical Policy Research and Development Aetna 151 Farmington Avenue Hartford, CT 06156 Cathy Moffitt, MD, FAAP, CHIE Chief Medical Officer Aetna 151 Farmington Avenue Hartford, CT 06156

Via email: ExecutiveResponseTeam@aetna.com

SUBJECT: Medical Policy Number 0016 "Back Pain – Invasive Procedures"

Dear Mr. Kane and Drs. Moffitt and McDonough,

On behalf of the American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS) and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN), we write to express our grave concerns regarding Aetna's coverage policy for CPT code 22853, which governs the use of spine cages in anterior cervical diskectomy and fusion (ACDF) surgery.

While every other commercial payer empowers surgeons and their patients to decide what implants are best suited for their cervical fusion surgery, Aetna remains the sole major commercial insurer that does precisely the opposite. The current Aetna coverage determination policy deprives patients and their surgeons of the ability to choose from various cervical interbody graft options that are either equivalent to or have superior surgical outcomes. After a comprehensive review of the current literature, it has become apparent to the AANS, CNS and DSPN that there is an immediate need for Aetna to reexamine and update its coverage determination policy that currently precludes the use of interbody cages in ACDF cases.

The offending policy is in Section H (*Intervertebral body fusion devices*), paragraph 2 of Aetna's Medical Policy Number <u>0016</u>, "Back Pain – Invasive Procedures," which delineates the exclusion of spine cage usage for routine cervical fusion, and states "[s]pine cages are otherwise <u>not considered medically necessary for cervical fusion because they have not been proven more effective than bone graft for this indication" (*Emphasis added*). Aetna remains the lone major commercial payer that limits polymer or metallic interbody spacers to neoplastic, adjacent segment levels or trauma cases requiring corpectomy, which represent the vast minority of circumstances. A blanket denial of the 22853 in routine ACDFs detrimentally impacts 85-90% of anterior cervical cases.</u>

The AANS, CNS and DSPN strongly contend that this policy unduly confines patient options, particularly in the light of innovations in cage design, material science and biomechanical understanding.

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1. Spine cages from earlier generations, utilizing materials like poly-ether-ether-ketone (PEEK) or titanium, have demonstrated comparable outcomes to structural allografts when used in ACDF cases.¹ In recent years, significant advancements have been achieved in the field of material science regarding cervical cage design. A prime example of this progress is the emergence of 3D-printed porous titanium cages. These porous titanium cages not only expedite bone conduction but also promote osteogenesis by stimulating bone formation and expediting bone integration, thereby enhancing the likelihood of successful implantation. The textured, roughened surface texture of the porous titanium cages encourages bone cells to integrate with and envelop the cage, facilitating fusion.^{2,3}

Additionally, the ability to tailor porous titanium cages to conform to vertebral endplate curvature diminishes the risk of subsidence. Furthermore, these cages can be optimized to align with the available vertebral endplate dimensions after cervical diskectomy. The research underscores that an increased implant-to-bone ratio within the anterior cervical spine interbody spaces substantially diminishes the likelihood of implant subsidence.^{4,5} The assortment of choices, spanning large to standard sizes of the customized spine cages, empowers surgeons to select an appropriate match for the patient's anatomy, which ensures optimal coverage of bony endplates, thereby minimizing subsidence while fostering osseointegration. Moreover, porous titanium cages have modulus of elasticity that is closer to the cortical bone, further decreasing its risk of subsidence.⁶

Biomechanical analyses confirmed that porous titanium cages mitigate the risk of subsidence and enhance stability by incorporating bone, leading to enhanced fusion outcomes. Recent clinical studies have also confirmed the benefit of 3D-printed titanium cages. A study by Singh et al. compared 3D-printed titanium cages and allografts in ACDF patients, revealing that the 3D titanium cage exhibited significantly lower subsidence rates and maintained superior segmental lordosis compared to allograft cages.

2. The employment of allografts carries inherent risks, including the potential transmission of life-threatening pathogens such as Creutzfeldt-Jakob disease. McVeigh et al. published a recent report of six patients infected with tuberculosis transmitted from cadaveric bone grafts. Moreover, processed cadaveric bone tends to be brittle, increasing the likelihood of fractures during insertion, particularly in cases of compressed disc spaces. Additionally, patients might harbor reservations about incorporating cadaveric bone into their bodies based on religious or cultural beliefs (e.g., Jehovah's Witness, Asian and Native American patients, respectively).

The ongoing denial of spine cage usage in ACDF cases has elicited substantial concerns within the neurosurgical community. For example, we are including the letter from a leading expert and past chair of the DSPN, Richard G. Fessler, MD, PhD, for Aetna's review. Dr. Fessler's letter to Aetna's former CEO best captures the sentiment of all the DSPN members regarding this issue.

Finally, it is impossible to reconcile Aetna's current coverage determination policy with the recently published literature alongside the coverage determination policies of other major commercial payers, including, for example, <u>United Healthcare</u>, <u>Cigna</u> and <u>Humana</u>. These payers rightly recognize ACDF with a polymer or metallic interbody spacer as scientifically sound and medically necessary. At the same time, out of the blue, Aetna determines that the spacer is now experimental and not medically necessary. As the literature continues to mount, demonstrating equivalency, if not superiority, Aetna's position becomes increasingly tenuous and unsupported by current scientific literature review standards. In our view, Aetna is prioritizing costs over patient safety rather than following the evidence as these other payers are doing. Aetna's lone position on the 22853 among all commercial payers has no other plausible explanation.

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On behalf of the AANS, CNS, DSPN and the patients we serve, we strongly urge Aetna to modify its restrictive coverage determination policy, which adversely affects patient well-being and inappropriately interferes with surgeon-patient autonomy in selecting treatment options. Technological progress highlights the advantages of incorporating cervical cages into anterior cervical fusion procedures, offering an equivalent, if not superior, alternative to cadaveric bone.

We welcome an updated and scientifically sound coverage determination policy from Aetna that empowers the surgeon and the patient to mutually decide on one of the most consequential decisions our patients have to make: what implant to use in their own bodies. Until then, our spine surgeons will continue to educate their patients about the differences between Aetna's anachronistic and discordant coverage policy and the scientifically sound coverage policies provided by other leading insurance companies. Furthermore, we will provide our patients with literature about the cervical spacer options that should be accessible to anyone undergoing a cervical fusion procedure.

Thank you for considering our views and request. We welcome the opportunity to meet with you to discuss our concerns with this policy further.

Sincerely,

Anthony L. Asher, MD, President

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American Association of Neurological Surgeons

Eric Potts, MD, Chair AANS/CNS Joint Section on Disorders of the

Spine and Peripheral Nerves

Elad I. Levy, MD, President Congress of Neurological Surgeons

Yi Lu, MD PhD, Chair

DSPN Payor Response Committee

Staff Contact

Catherine Jeakle Hill, Director, Regulatory Affairs AANS/CNS Washington Office 25 Massachusetts Avenue, NW, Suite 610 Washington, DC 20001

Phone: 202-446-2026 Fax: 202-628-5264

Email: chill@neurosurgery.org

Enclosure: July 13, 2023, letter from Dr. Richard G. Fessler to former Aetna CEO Mark Bertolini

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University Neurosurgery Rush University Medical Center Professional Building 1725 W. Harrison St., Suite 855 Chicago, IL 60612

Tel: 312.942.6644 Fax: 312.942.2176 www.rush.edu



Richard G. Fessler, MD, PhD Rush University Medical Center Professor

July 13, 2023

Mark Bertolini, CEO Aetna Insurance Company

To Whom It May Concern:

Recently your insurance company denied a "standard of care" treatment (utilization of a "cage" for cervical fusion) for a patient requiring cervical disc surgery. Despite completing a "peer-to-peer" conference Aetna still denied the use of cervical cages for this fusion. This has been a standard of care for over 30 years. Instead, you demanded that this patient receive either autologous iliac crest bone (which is associated with multiple complications) or allograft bone (which exposes the patient to potential life-threatening infections such as Jakob-Creutzfeld disease). This is clearly unethical and essentially practicing medicine without a license. It is an abusive practice which is now becoming a daily event for practicing physicians. This not only denies state of the art treatment for necessary medical procedures, it causes undue stress on a group of patients who are already dealing with medical illnesses. On the physician side, it compounds the financial and administrative burden on physicians who find themselves with increasingly less time to spend actually caring for patients, and unnecessarily adds to the overall cost of medical care. I strongly object to this unethical practice. To that end I am bringing this to the attention of my United States senators and to the patients Congressperson.

Sincerely,

Richard G. Fessler, M.D. PhD

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Professor