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Chief Medical Officer Aetna

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April 26, 2024

Dear Mr. Kane and Drs. Marans, Fitzgerald, Moffit and McDonough,

The aforementioned societies would like to request a change in Aetna's policy (https://www.aetna.com/cpb/medical/data/1_99/0016.html) to allow/include coverage for the use of biomechanical interbody devices in all Anterior Cervical Discectomy and Fusion (ACDF) surgeries.

Multiple physician societies have engaged Aetna in teleconferences, over many years, to discuss the relevant medical literature. Although our opinions differ on this matter, with Aetna maintaining that the literature presented is not compelling enough to modify their policy, we have appreciated the opportunity to converse with Aetna to this regard.

Aetna, however, continues to be the only insurance carrier who does not recognize the use of these devices as "standard of care" and who continues to restrict the use of biomechanical devices. This has created significant issues which need to be discussed and addressed. We would like to focus on these issues including unfair access restrictions, availability, and the practice of modern spinal surgery.

The undersigned leaders represent multiple spinal surgical societies raising the concern to Aetna regarding their long-standing policy of excluding coverage for biomechanical interbody devices in the cervical spine for use in Anterior Cervical Discectomy and Fusion (ACDF) surgeries. As has been raised to Aetna by these societies individually, over the last decade, in phone calls and letters, Aetna's policy of exclusion not only creates a bad faith environment but creates unfair burdens to patients, providers, and health care facilities, and is inconsistent with Aetna's own policies.

- inconsistency with Aetna's own policies
  - allow structural spacers of graft and other biomechanical material in lumbar spine (LIFs) and in corpectomies
- inconsistency with the business/other payors
  - Aetna is the only major payor denying these devices
- inconsistency with Medicare Advantage requirements
  - Aetna has a Medicare Advantage program and as such, they cannot have any coverage less than Medicare's coverage
  - Medicare Advantage plans must follow CMS guidelines in the US, according to federal law
- subset of patients who do not want allograft (include for their cited cultural/religious beliefs) for whom autograft is not a reasonable option based on surgeon/patient discussions and shared decision-making.
- burden of bone bank requirements for allograft use: most hospitals are not bone banks

Furthermore:

<u>Violation of surgeon/patient relationship</u>

The current Aetna policy creates a deviation from standard discussions, whereby a surgeon must explain to Aetna-enrolled patients, why synthetic cages are used for, and considered standard of care for, almost all other patients undergoing ACDF, but for Aetna-enrollees, structural bone graft is the only allowable option. There is certainly a psychological cost to the patient and this also

undermines and damages the physician/patient relationship. It should not be the surgeon's responsibility to justify an insurance company policy, especially when the surgeon does not believe it is the best available option for the patient, it does not benefit patient care and is out of line with all other major payors including CMS. This is why we believe that Aetna is acting in bad faith to not only their insured but to their contracted providers.

Because structural allograft is a cadaveric tissue, it often has imperfections. These imperfections often lead to failure/fracture of the allograft. When these patients fracture or go on to pseudoarthrosis, this results in additional surgical procedures and *. It creates a situation of mistrust where the patient feels they did not initially receive the best surgical option. Additionally, reoperation is costly to the patient and to Aetna and the occurrence of anatomic injury to structures surrounding the cervical spine is higher due to the presence of scar tissue formation.

*Noted in Aetna's 2023 response to AANS/CNS's letter is Aetna's knowledge of the Jain et al 2020 paper identifying a higher rate of reoperation in the allograft group over the PEEK group. (Attached)

Aetna's reply also has stated lack of knowledge of religious impact on use of allograft; it is not the role of the physician to interrogate the patient on the origin of their stated beliefs. It should suffice for Aetna, as it does for the surgeon, that the patient cites a preference. It is well-documented and known that religions such as Jehovah's Witness do not accept organ or tissue transplant. These patients may also have medical conditions which render the use of structural autograft less preferable.

<u>Outdated standards/technologies</u>
We urge Aetna to update their policy to reflect current, best practices, which is also the current standard of practice, that allows access for patients to current innovative technology and treatments , and not rely on decades of outdated standards. Aetna certainly could separate out titanium/metal cages from PEEK cages, as they review the data of biomechanical implants. Regarding bone grafts and biologics, Aetna can reasonably allow products that are both cost-effective and have sufficient literature.

<u>Oversimplification of the quality and cost in allograft use</u>
Structural allograft can have unseen cracks in the bone which may lead to failure; further, each graft is unique, and may come from different donors varying in size and bone density. Each synthetic cage is consistent. Structural allografts require thawing, adding to OR time and therefore, OR costs. Preparation and loading of biomechanical implants is readily reproducible for operating scrub technician assisting with preparation of the implants. Regional differences exist in cost structure, and in some locales, allograft is significantly more per level than synthetic cage. Additionally, grafts need to be flown in/out for cases, expanding the environmental footprint of this needlessly, burdensome process to which Aetna's policy adds.

The time has come for Aetna to change their policy regarding synthetic cages in the cervical

spine and we the undersigned societies would like the opportunity to work with Aetna on an updated policy with access to current innovative technology for patient care.

Respectfully,

North American Spine Society (NASS)

American Academy of Orthopaedic Surgeons (AAOS)

American Association of Neurological Surgeons (AANS)

AANS/CNS Section on Disorders of the Spine and Peripheral Nerves (DSPN)

Cervical Spine Research Society (CSRS)

Congress of Neurological Surgeons (CNS)

International Society for the Advancement of Spine Surgery (ISASS)

Scoliosis Research Society (SRS)

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