

May 24, 2018

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National Medical Director for Coverage Policy
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Via e-mail: Julie.Kessel@Cigna.com

Subject: Medical Coverage Policy 0527 Cervical Fusion

Dear Dr. Kessel,

The American Association of Orthopaedic Surgeons (AAOS), American Association of Neurological Surgeons (AANS), Cervical Spine Research Society (CSRS), Congress of Neurological Surgeons (CNS), AANS/CNS Joint Section on Disorders of Spine and Peripheral Nerves (DSPN), International Society for the Advancement of Spine Surgery (ISASS) and North American Spine Society (NASS), appreciate the opportunity to provide our comments on the Cigna Medical Coverage Policy 0527 Cervical Fusion. The policy discussion is well done and provides a good review of the extant literature. However, the recommendations for coverage do not comply with standard spine practices or with the literature reviewed.

We would suggest the following changes (**listed in bold type**):

1. Page 2, CERVICAL FUSION FOR IATROGENIC INSTABILITY: Add a fourth indication, **“following extensive cervical laminectomy.”**

Rationale: The literature supports the incorporation of stabilization to multi-level cervical laminectomy procedures performed for cervical stenosis^{6,7}

2. Page 2, CERVICAL FUSION FOR INSTABILITY: SPINAL STENOSIS: Change element 2 to read as follows: “failure of at least three (3) consecutive months of physician-supervised conservative medical management including exercise, nonsteroidal and/or steroidal medication (unless contraindicated), physical therapy and activity lifestyle modification in the absence of **clinically significant myelopathy.**”

Rationale: The presence of significant myelopathy likely will not respond to physical therapy, NSAIDs, lifestyle modifications, and other conservative interventions. Forcing patients to wait for three months or greater may allow for progression of myelopathy and lead to greater degree of permanent disability.¹

3. Page 3, CERVICAL FUSION NOT MEDICALLY NECESSARY: Change the first bullet to read: “...with initial primary **foraminotomy**/discectomy for nerve root decompression or spinal stenosis in the absence of spondylolisthesis or kyphosis”. **Strike bullet #2, “treatment of spinal stenosis in the absence of spondylolisthesis or spinal instability,” and bullet #4:**

“posterior cervical fusion performed with laminectomy in the absence of kyphosis (e.g., degenerative spine) or subluxation/translation of more than 3.5 mm.”

Rationale: the literature supports the incorporation of stabilization to multi-level cervical laminectomy procedures performed for cervical stenosis^{6,7}

Discussion

We appreciate the thoughtful review of the cervical literature provided in the Cigna Cervical Fusion Medical Coverage Policy for Cervical Fusion. However, the document does not appropriately reflect the extant literature, nor does it reflect present clinical practice. Our objection is not with the literature; the Cigna bibliography is quite good. Unfortunately, the policy as presently developed by Cigna does not reflect the literature reviewed.

Our key area of dissent is with the policy's failure to allow the incorporation of a posterior cervical fusion procedure at the time of initial laminectomy in patients with cervical stenosis but no evidence of kyphosis, cervical degenerative subluxation of over 3.5 mm, or other evidence of preexistent cervical instability. The policy, as written, represents a substantial change in clinical practice and does not reflect best practices. These changes in clinical practice would potentially expose Cigna enrollees to high rates of post-laminectomy kyphosis, chronic pain, and risk for late clinical deterioration. This policy may limit appropriate access to best spine surgery options for Cigna enrollees.

Indications

As noted in the “Indications” portion of the policy document, multiple cervical foraminotomies and extensive facet resections may produce cervical instability. The article by Komotar et al., cited in the text, however, notes further that “...recognizing the potential for spinal instability is essential to prevent neurologic compromise and intractable axial neck pain caused by deformity progression.” This article notes that isolated laminectomy in patients with evidence of profound cervical instability (subluxation of 3.5 mm or more, 11 degrees of kyphosis, or greater than 4 mm of motion on dynamic views) will not be successful. However, these authors also note that iatrogenic deformity after cervical laminectomy procedures is “...one of the more common causes of progressive cervical kyphosis.” Furthermore, these authors note that posterior exposure causes denervation of cervical paraspinal muscles and may produce facet compromise through disruption of the facet capsules without direct bony disruption. The number of lamina resected may increase the risk of post-laminectomy kyphosis, and laminectomy in patients under the age of 18 may produce progressive kyphosis in over 50% of patients. Other series note incidence of post-laminectomy kyphosis of up to 40%.⁶ Twenty-five percent of patients in a series compiled by Herkowitz developed significant kyphosis within two years of surgery. Of note, the worst clinical outcomes in this series were in the laminectomy cohort.⁴ Recognizing the risk of development of iatrogenic deformity in patients treated by cervical laminectomy, Komotar et al., conclude “The ***potential*** or presence of instability must be recognized and prevented with a supplemental stabilization technique” [emphasis added].⁶

With regard to the “Cervical Decompression Procedures” and “Professional Societies/Organizations” portions of the discussion in the policy document, we would agree with the opinion of Bono et al., that posterior cervical fusions should not be routinely performed in the treatment of cervical radiculopathy.² However, posterior cervical decompressions for radiculopathy are usually performed unilaterally and at 1 or 2 levels. Structurally, this is considerably different than a multilevel, bilateral decompression as is routinely performed in cases of cervical stenosis. McAlister et al., cited in the “Cervical Decompression Procedures” portion of the discussion, notes a higher complication rate long-term in patients treated with laminectomy alone. These authors do not make a clear recommendation about laminectomy or laminectomy with fusion, concluding that “the decision to perform cervical laminectomy or

laminectomy/fusion should be made on an individualized basis with the patient understanding the risks and clinical benefits of each.”⁷ Bono et al., note that “...decompression and fusion appears to be indicated for multilevel stenosis resulting in myelopathy.”² The addition of a cervical fusion to cervical laminectomy procedures is considered best practice and, for many researchers, standard of care. Fehlings et al., reporting an AO Spine North America-sponsored multi-center study of the clinical efficacy of anterior and posterior decompressions for cervical spondylotic myelopathy, only considered posterior cervical decompression procedures that either entailed posterior element reconstruction via laminoplasty or included fusion procedures. Isolated cervical laminectomy was not considered a viable treatment option.³ This parallels the clinical opinions of the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves, which note the potentially high rate of post-laminectomy instability producing late neurological deterioration.⁵ This group of authors observes that cervical laminectomy and fusion is not associated with late deformity (Class III evidence).

Conclusion

The current policy as written is not in keeping with best practices for surgeons. The policy change is not supported by the current literature. Limiting the role of cervical fusion at the time of initial laminectomy potentially places Cigna enrollees at risk for post-laminectomy kyphosis, chronic pain, and late deterioration. We strongly recommend that surgeons practice in-line with the most current available literature and have the option to incorporate a fusion at the time of initial laminectomy. We, therefore, request that you adopt our recommendations before implementing the new policy.

Thank you for considering our comments.

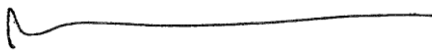
Sincerely,



Shelly D. Timmons, MD, PhD, President
American Association of Neurological Surgeons



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



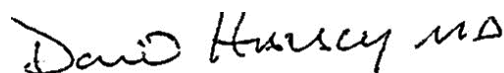
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