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AANS and CNS Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN) Comments on NASS Coverage Policy Recommendations on Lumbar Interspinous Device without Fusion and Decompression

The American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) Joint Section on Disorders of the Spine and Peripheral Nerves (DSPN) appreciates the opportunity to provide comments on the North American Spine Society (NASS) coverage policy recommendations on Lumbar Interspinous Device without Fusion and Decompression. Below in italic print are recommendations from the NASS document followed by our comments in bold.

Interspinous devices (ISP) have been used previously for the purpose of indirect decompression without laminectomy through spinous process distraction. Importantly these coverage recommendations are for interspinous devices without fusion in conjunction with a direct decompression in the form of a lumbar laminectomy for patients with neurogenic claudication or radiculopathy secondary to spinal stenosis. Coflex for example is specifically approved for this indication. Interspinous fusion is importantly excluded.

AANS/CNS Joint Section on DSPN Comment:

The title of the policy may cause confusion. We suggest the title be changed to: “Lumbar Interspinous Device without Fusion *in conjunction with Decompression*” or alternatively “Decompression without Fusion when using Lumbar Interspinous Process Devices”. Either one of these alternate titles clearly indicates that the surgeon is performing a decompression.

Stabilization with an ISP without fusion in conjunction with laminectomy may be indicated as an alternative to lumbar fusion for degenerative lumbar stenosis with or without low grade spondylolisthesis (less than or equal to 3mm of anterolisthesis on a lateral radiograph) with qualifying criteria when appropriate:

- 1. Significant mechanical back pain is present (in addition to those symptoms associated with neural compression) that is felt unlikely to improve with decompression alone. Documentation should indicate that this type of back pain is present at rest and/or with movement while standing and does not have characteristics consistent with neurogenic claudication.*
- 2. A lumbar fusion is indicated post-decompression as recommended in the NASS Coverage Recommendations for Lumbar Fusion.*
- 3. A lumbar laminectomy is indicated as recommended in the NASS Coverage Recommendations for Lumbar Laminectomy.*

AANS/CNS Joint Section on DSPN Comment:

The indications listed in the NASS coverage position are supported by the experience in the literature.

Interspinous (ISP) devices are NOT indicated in cases that do not fall within the above parameters. In particular, they are not indicated in the following scenarios and conditions:

1. *Degenerative spondylolisthesis of grade II or higher*
2. *Degenerative scoliosis or other signs of coronal instability*
3. *Dynamic instability as detected on flexion-extension views demonstrating at least 3 mm of change in translation*
4. *A fusion is otherwise not indicated as per the NASS Coverage Recommendations for Lumbar Fusion*
5. *A laminectomy is otherwise not indicated as per the NASS Coverage Recommendations for Lumbar Laminectomy*

AANS/CNS Joint Section on DSPN Comment:

The exclusion criteria are for the most part reasonable. ISP devices are not meant to be applied for the purpose of stabilizing an unstable spinal segment and are not meant to be a replacement for spinal fusion in the presence of spinal instability. Item number 4 above would seem to imply that the use of an ISP device is only indicated if the patient also meets the NASS Coverage Recommendations for Lumbar Fusion. Below in italics we have listed these recommendation and included our notes on each of these in parenthesis.

1. *Dynamic instability is present as documented by flexion-extension radiographs or comparison of a supine and upright image, defined as a difference in translational alignment between vertebrae greater than 2 mm between views.*

AANS/CNS Joint Section on DSPN note: This is essentially an exclusion criteria for the use of an ISP device

2. *Spondylolisthesis (defined as at least 1-2 mm of anterolisthesis of the upper vertebra in relation to the lower vertebra) is present, either isthmic (i.e. secondary to a posterior arch stress fracture) or degenerative type.*

AANS/CNS Joint Section on DSPN: note spondylolisthesis greater than 3 mm is a contraindication to the use of an ISP device.

3. *Cases in which decompression will likely result in iatrogenic instability, such as foraminal stenosis, during which greater than 50% of facet joint will be removed to adequately decompress the exiting nerve root.*

AANS/CNS Joint Section on DSPN note: iatrogenic instability would also be a contraindication to the use of an ISP device

4. *Adjacent level disease, stenosis that has developed at a level above or below a previous fusion.*

AANS/CNS Joint Section on DSPN note: that it is questionable that an ISP device could be used for this indication and it was not studied in the trials

5. Recurrent stenosis, e.g. that which developed at a level that has been previously operated

AANS/CNS Joint Section on DSPN note: that this is also not an indication for the use of an ISP device

We are concerned that cross-referencing to the NASS lumbar fusion coverage recommendations may lead to potential confusion for the use of the ISP device. We suggest the fourth contraindication above--A fusion is otherwise not indicated as per the NASS Coverage Recommendations for Lumbar Fusion—be removed or modified.

Thank you for considering our comments. We hope our feedback on the NASS Coverage Policy Recommendations on the Decompression without Fusion when using Lumbar Interspinous Process Devices coverage position are helpful. Please let us know if we can provide any additional information. If at all possible, we would appreciate a greater period of time to provide a response for future coverage positions.

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