Interspinous Device without Fusion

NASS
NORTH AMERICAN SPINE SOCIETY

DEFINING APPROPRIATE COVERAGE POSITIONS

COVERAGE TASKFORCE

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Introduction

North American Spine Society (NASS) coverage policy recommendations are intended to assist payers and members by proactively defining appropriate coverage positions. Historically, NASS has provided comment on payer coverage policy upon request. However, in considering coverage policies received by the organization, NASS believes proactively examining medical evidence and recommending credible and reasonable positions may be to the benefit of both payers and members in helping achieve consensus on coverage before it becomes a matter of controversy.

Methodology

The coverage policies put forth by NASS use an evidence-based approach to spinal care when possible. In the absence of strict evidence-based criteria, policies reflect the multidisciplinary and non-conflicted experience and expertise of the authors in order to reflect reasonable standard practice indications in the United States.

NASS Coverage Policy Methodology

Scope and Clinical Indications

There is a growing number of interspinous distraction devices available on the market today. These include static (i.e. non-flexible or compressible) devices, such as the X-STOP implant, and dynamic implants, such as the Co-Flex. Static devices are typically used to provide indirect decompression of the neural elements. Some dynamic devices, such as the Co-Flex, according to its FDA labeling and available published data, are intended to be used in conjunction with a laminectomy. For the purposes of this document, recommendations will apply only to static (i.e. non-flexible) devices that are intended to be used *instead of* a direct decompressive procedure.

Interspinous distraction devices without fusion may be indicated for the following diagnoses with qualifying criteria, when appropriate:

1. Degenerative lumbar stenosis:
    - **a.** associated with neurogenic claudication that is relieved by lumbar flexion
    - **b.** patients over 50 years old
    - **c.** failure of nonoperative treatment
    - **d.** no more than 25 degrees of degenerative scoliosis
    - **e.** no more than a grade I degenerative spondylolisthesis

f. open surgery (e.g. laminectomy) is not a medically safe treatment option because of comorbidities

Interspinous distraction 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:

- degenerative spondylolisthesis of grade II or higher
- degenerative scoliosis greater than 25 degrees dynamic instability at the operative level
- symptoms are not relieved by flexion
- patient is medically suitable for a direct decompressive procedure (e.g. laminectomy)
- patient has primarily axial back pain that is unrelated to activity
- patients younger than 50 years old

Rationale for Coverage Recommendation

Patients with lumbar spinal stenosis can present with neurogenic claudication. Though nonoperative treatment is usually attempted first, numerous studies have shown that surgical treatment is superior to nonoperative treatment for patients with symptomatic spinal stenosis with or without spondylolisthesis. The gold standard surgical treatment has been decompression with or without fusion[4, 6, and 11].

In the early 2000s, interspinous distraction devices for indirect decompression were proposed as a treatment option for patients with lumbar spinal stenosis. In an industry sponsored, multi-center, randomized controlled trial, Zucherman et al compared outcomes of the X-STOP interspinous device to nonoperative treatment in patients with neurogenic claudication from lumbar stenosis. Inclusion criteria were age 50 years or older, lumbar spinal stenosis at 1 or 2 levels, neurogenic claudicant symptoms (inferred) that were relieved by forward flexion, and the ability to walk at least 50 feet. The X-STOP group scored superior in all metrics at 2 years compared to the nonoperative control group. The authors concluded that that in the continuum of treatment options, this interspinous distraction device offers an attractive alternative to both nonoperative care and decompression surgery, though the latter was not a direct comparator in this study[12]. In a more recent randomized clinical trial comparing open decompression to X STOP in 100 patients, Stromqvist (Stromqvist et al, Spine 38: 1436-1442) found similar results between the two procedures, though there was a higher reoperation rate in the X STOP group (26% versus 6 %).

The efficacy of an interspinous distraction device for patients with stenosis and degenerative spondylolisthesis has been reported. Retrospectively analyzing a subgroup of patients with grade I spondylolisthesis from the pivotal prospective, randomized controlled trial by Zucherman et al, Anderson et al reported significant improvements in all parameters in the X-STOP group compared to

the control group[1]. In the Stromqvist et al RCT (Stromqvist et al, Spine 38: 1436-1442), the group found no difference in outcomes between patients with or without grade I spondylolisthesis.

The mechanism of action of interspinous distraction devices has been studied as well. In one study, Nandakumar et al reported that spinal canal diameter was found to increase significantly post X-STOP implantation and that dural sac diameter increases were maintained at 2 years follow-up[4]. In critique of this study however, there was little correlation between increases in spinal dimension and outcomes, with substantial overlap between groups that had improvement and did not have improvement. Addressing concerns of producing local kyphosis, Schulte et al evaluated 20 patients who had undergone X-STOP implantation for overall spinal balance on full-length films. The authors found that it did not seem to be detrimental to sagittal balance[7]. Finally, Siddiqui et al evaluated 26 patients with postoperative positional MRI scans in the standing, supine and sitting flexion and extension positions. Significant increases in dimensions of the neural foramen and canal area were demonstrated after surgery. The authors concluded that at the device can improve the degree of central and foraminal stenosis in vivo[8, 9].

Despite these positive data, Epstein reported a review of the literature on complication rates, reoperation rates and outcomes for implantation of interspinous devices. Additionally, they reviewed their institution's clinical and cost experience with these devices implanted in 16 patients. Their report, based on a review of the literature in patients followed an average of 23-42.9 postoperative months, revealed a complication rate ranging from 11.6-38%, a 4.6-85% reoperation rate, and a 66.7-77% rate of poor outcomes. They calculated an average cost of over $18,500 per device in their institution. Given these observed complication rates, reoperation rates, poor outcomes and high costs, Epstein concluded that the use of this device remained controversial and should be investigated further before widespread adoption[2].

Considering these available data, it seems prudent to allow coverage of an interspinous distraction device without direct decompression or fusion in a select group of patients as detailed above. This coverage might be best considered conditional until further evidence is considered in the future.

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