Interspinous Fixation with 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

Interspinous fixation devices have been marketed as an alternative to pedicle screw fixation for lumbar fusion. The suggested benefits of these devices have been less invasive exposure for implantation and diminished implantation risks as compared to pedicle screws. Some of these devices are flexible/compressible, while others are static, non-compressible type implants. For the purposes of this document, recommendations will apply to any device that includes fixation to the spinous processes for the purposes of stabilizing the motion segment to augment fusion (either anteriorly or posteriorly). There are other interspinous devices that are intended to provide distraction in order to achieve indirect decompression without fusing/stabilizing the motion segment. These are considered in another coverage document (**Lumbar interspinous distraction devices without fusion for indirect decompression**). Others are intended to provide stabilization without fusion in patients who have undergone direct decompression. These are not covered in the current document.

Interspinous fixation with fusion for stabilization is currently NOT indicated as an alternative to pedicle screw fixation with lumbar fusion procedures.

Rationale for Coverage Recommendation

Despite the growing popularity of interspinous fixation devices for fusion, there is a dearth of published literature on outcomes for use in this way. There is a growing body of literature concerning the use of interspinous devices as so-called "soft stabilization" following direct decompression (e.g. laminotomy/laminectomy) without fusion. However, there is limited, low-level evidence published about outcomes of devices that are purportedly to be used for stabilization of a motion segment. To our knowledge, there are no prospective, randomized, controlled trials evaluating the efficacy or safety of this class of devices compared to the gold standard (pedicle screws) with sufficient follow-up. Though not a comprehensive list, these include the Coflex-F, Aspen, and SPIRE devices.

In one retrospective study published in the Korean literature[3], 40 patients who underwent interspinous fixation and TLIF with the SPIRE device (Medtronic) were compared to 36 patients who underwent pedicle screw fixation and TLIF. Patients had a variety of degenerative diagnoses. Overall, they found no significant differences in radiographic or clinical outcomes. In critique of the study, there was some heterogeneity in the underlying diagnoses of the two groups, with 7 patients in the pedicle screw group having foraminal stenosis compared to none in the SPIRE group. Furthermore, the nature of technique of decompression was not well described.

Kasai et al (Journal of Orthopaedic Surgery and Research 2008) reported on 31 patients with either spinal stenosis (27 patients) or spondylolisthesis (4 patients) who underwent stabilization with the Tadpole system and posterolateral fusion. Follow-up was 2 years. This group reported JOA improvements in the cohort. The mean operative time was 79 min and mean time for spinal instrumentation was 8 minutes. A 93.5% fusion rate was documented; 1 case of device displacement was reported.

Wang et al (J Neurosurg Spine 2006 Feb) reported outcomes of patients who underwent ALIF and posterior stabilization with either the SPIRE device (21 patients) or pedicle screws (11 patients). The mean operative time and blood loss was less in the SPIRE group. No complications, pseudarthrosis, or hardware failure were noted in any patient at 4.9 to 7.2 months follow-up. In a similarly small study, Tomii retrospectively reported on a series of 15 patients with spondylolisthesis who underwent placement of an S-plate fixation during concurrent posterior interbody fusion. They demonstrated neurological improvements postoperatively as measured by JOA scores. A 100% fusion rate was documented and no complications.

Though of limited clinical significance, biomechanical studies have shown mixed results regarding the equivalency between interspinous fixation devices and pedicle screws. Techy et al found no difference in an interbody spacer model between pedicle screws and interspinous fixation in flexion/extension. With lateral bending and axial rotation, however, pedicle screws were superior. Karahalios et al, using an ALIF model with an interspinous fixation device (Aspen), similarly found that the new device was less effective in lateral bending and axial rotation than pedicle screws.

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Author Disclosures

William Tontz, MD: Device or Biologic Distributorship (Physician-Owned Distributorship): Phygen (C, Paid directly to institution/employer); Stock Ownership: Phygen (1 Shares, 0.6%, Physician owned implant company involved in development and distribution of spinal implants. , Paid directly to institution/employer); Consulting: Medtronic (Financial, 25000, Paid directly to institution/employer); Speaking and/or Teaching Arrangements: SpineArt (Financial, 5000); Trips/Travel: Medtronic (Financial, 7800); Scientific Advisory Board: Medtronic (Financial, see prior payments through medtronic).