Percutaneous Thoracolumbar Stabilization



DEFINING APPROPRIATE COVERAGE POSITIONS



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

Appropriate consideration for most of the *same diagnoses* for which an open thoracolumbar or lumbar stabilization with pedicle screws is indicated. We would refer the reader to the Lumbar Fusion Coverage Recommendations for a comprehensive list of the diagnoses with qualifying criteria. In addition to fulfilling the requirements of the Lumbar Fusion Coverage Recommendations, there are specific considerations and qualifying criteria for Percutaneous Thoracolumbar Stabilization (PTS). The diagnostic list below details those considerations. Importantly, this coverage recommendation refers to instrumentation only (i.e. percutaneous pedicle screws), which may or may not be used in conjunction with a thoracic, thoracolumbar, or lumbar fusion. In developing this coverage recommendation document, we have included cases in which PTS may be considered a safe and effective alternative to open pedicle screw placement.

- 1. **Infection** (including tuberculosis) involving the spine in the form of discitis, osteomyelitis, or epidural abscess
- 2. **Tumor** involving the spine or spinal canal

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- 3. **Traumatic** Injuries, including fractures, fracture-dislocations, dislocations, or traumatic ligamentous disruption
- 4. **Deformity** that includes the thoracic, thoracolumbar, or lumbar spine
- Degenerative Conditions, including Stenosis, Disc Herniations, Synovial Facet Cysts, and Discogenic Low Back Pain

Percutaneous Thoracolumbar Stabilization is NOT indicated in cases that do not fulfill the above criteria. Of note, it is not indicated in the following scenarios:

- Cases in which intraoperative image guidance (either by fluoroscopy or computer navigation) is not feasible
- Cases in which the patient's anatomy is not amenable to safe containment of available pedicle screw implants

Rationale

Pedicle screw stabilization is one of the most commonly performed procedures in spinal surgery. The percutaneous approach of screw insertion has steadily gained traction over recent years with an increased number of publications documenting its safety and efficacy in various applications. With some exceptions, pedicle screws are used as a stabilizing method in conjunction with spinal fusion. As such, the proposed coverage recommendations put forth in this document by the North American Spine Society are contingent upon a patient fulfilling the criteria described in the **Lumbar Fusion Coverage Recommendations**. In short, for a patient to be considered eligible for percutaneous thoracolumbar stabilization (PTS), the criteria detailed for lumbar fusion must be first met. The following discussion of the items listed above considers the *equivalence* of PTS as an *acceptable alternative* to open pedicle screw insertion. Coverage recommendations put forth by the North American Spine Society utilizes an evidence-based approach to spinal care when possible. In the absence of strict evidence-based criteria, the Policy utilizes the multidisciplinary and non-conflicted experience and expertise of the task force in order to reflect reasonable standard practice indications in the United States.

In item 1, the use of PTS for spinal infections should have similar indications to open pedicle screw fixation. In the treatment of osteomyelitis, there is often significant destruction of the vertebral bodies that may be treated by corpectomy and subsequent posterior stabilization. Open pedicle screw placement is the usual form of posterior stabilization. Considering the potential for less blood loss,

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percutaneous pedicle screw placement would be a reasonable alternative in such a scenario. Deininger et al (Acta Neurochir, 2009) reported feasibility and effectiveness of PTS for the treatment adult pyogenic spondylodiscitis in a small series (8 patients). Of note, their technique did not include any corpectomy and was therefore only a stabilization procedure.

In item 2, there are few, if any data, reporting the use of PTS for the treatment of spinal tumors. However, there is no logical reason to believe that the utility of percutaneously inserted screws would be different than for screws inserted with open technique. Similar to the rationale for item 1 (infections), spinal tumors are often resected via an anterior corpectomy that often benefit from posterior stabilization of some form. The potential benefits of decreased blood loss and incision size with PTS in medically compromised patients with spinal metastases could be significant.

In item 3, there is a rapidly growing body of evidence demonstrating safety and efficacy of PTS for the treatment of spinal fractures and dislocations. Subscribing to the advantages of so-called damage controlled orthopaedics, including spine care (Stahel et al, J Trauma Acute Care Surg, 2013), in which temporary, percutaneous fixation of unstable injuries can have overall medical benefits to the patient from early mobilization, PTS appears to have a clear role. Moreover, PTS has a particular role for spinal injuries as they are often treated with stabilization alone (i.e. no fusion). Numerous reports have documented safety and efficacy of percutaneous pedicle screw fixation for the treatment of spinal fractures. In a PRCT, Jiang et al (J Int Med Res, 2012) found PTS to be a reasonable alternative to open surgery for injuries in which postural reduction could be achieved, while open surgery appeared to be better for patients who required more significant reduction maneuvers. Ni et al (J Spinal Disord Tech, 2010) documented reasonable outcomes with short-segment percutaneous pedicle screw fixation of 36 patients with thoracolumbar burst fractures. In a non-randomized, prospective comparative study, Wang et al (Chin J Traumatol, 2010) found no significant clinical or radiographic differences between patients treated with open fixation and PTS except for anterior vertebral body height, which was significantly better in the open surgery group.

In item 4, there is a limited role of PTS for the treatment of spinal deformity. Particularly in adult deformities in which curves can be quite stiff, open techniques of release and/or osteotomy have resulted in the greatest deformities corrections. With growing experience of minimally invasive surgical techniques in which releases can be performed through smaller incisions, percutaneous pedicle screws may play a role in achieving and maintaining deformity correction. At the current time, it is difficult to define exactly which patients are the best candidates for PTS of spinal deformities. Wang (J Neurosurg

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Spine, 2013) recently reported the results of 25 patients with thoracolumbar scoliosis treated with multi-level facet osteotomies, expandable interbody cages, and percutaneous pedicle screw stabilization. The author documented a mean ODI improvement of 20.8 points and improved back and leg VAS pain at 12 months. The authors also reported substantial correction of lumbar lordosis (27.8 degrees to 42.6 degrees) and sagittal balance, both parameters having been previously reported to correlate with clinical outcome. They did report 2 cases of hardware requiring repositioning and one case of screw pullout, among other complications. Isaacs et al (Spine, 2010), in a prospective nonrandomized study of 107 patients with degenerative scoliosis, compared patients who underwent an XLIF procedures with or without supplemental percutaneous pedicle screw stabilization. Though not matched for curve severity, they documented a higher rate of major complications in the pedicle screw group (20.7%) than the stand-alone XLIF group. Anand et al (J Spinal Disord Tech, 2008) reported good outcomes in twelve patients with degenerative scoliosis who underwent percutaneous pedicle screw fixation and in conjunction with other percutaneous interbody fusion techniques, with acceptable complication rates, operative times, and blood loss.

In item 5, there is also a growing body of evidence demonstrating that the goals of traditional open surgery for a variety of degenerative lumbar conditions requiring fusion can be achieved in many cases via less invasive techniques. For most of these maneuvers, percutaneous pedicle screw stabilization is performed as well. For example, Ahadian et al (J Neurosurg Spine, 2013) used a less invasive retroperitoneal approach for lumbar interbody fusion for patients with grade I and II L4-5 spondylolisthesis. In all cases, percutaneous screws were used to stabilize the segment, documenting reasonable safety and clinical outcomes. Chen et al (Neurosurg Focus, 2013) described a technique for tube-assisted decompression followed by TLIF augmented by percutaneous screws for patients with degenerative spondylolisthesis. Tang et al (Turk Neurosurg, 2012) reported good 4 year clinical and radiographic outcomes of 47 patients in whom an ALIF and percutaneous pedicle screws was performed for so-called degenerative lumbar instability. Kotani et al (Eur Spine J, 2012) compared open versus MIS-TLIF (the latter utilizing percutaneous pedicle screws) in 80 patients with degenerative spondylolisthesis and stenosis. Notwithstanding study limitations, the authors reported better clinical outcomes in the minimally invasive group. Other groups have also reported reasonable outcomes with ALIF stabilized by percutaneous pedicle screws in patients with varying types of degenerative lumbar disorders (Anderson et al, Eur Spine J, 2011; Agrillo et al, J Neurosurg Sci, 2010)

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Author Disclosures

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