Lumbar Fusion

NASS NORTH AMERICAN SPINE SOCIETY

DEFINING APPROPRIATE COVERAGE POSITIONS

COVERAGE TASKFORCE

North American Spine Society 7075 Veterans Blvd. Burr Ridge, IL 60527

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

Lumbar fusion may be indicated for the following diagnoses with qualifying criteria, when appropriate.

1. **Infection** (including tuberculosis) involving the spine in the form of discitis, osteomyelitis, or epidural abscess in EITHER of the following cases:
    a. instability is present
    b. debridement and/or decompression is anticipated to result in instability
2. **Tumor** involving the spine or spinal canal in EITHER of the following cases:
    a. instability is present
    b. resection and/or decompression is anticipated to result in instability
3. **Traumatic** Injuries, including fractures, fracture-dislocations, dislocations, or traumatic ligamentous disruption in EITHER of the following cases:
    a. instability is present
    b. decompression of the spinal canal is anticipated to result in instability

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4. **Deformity** that includes the lumbar spine (e.g. scoliosis that is restricted to the lumbar spine or a thoracolumbar deformity that ends in the lumbar spine) that meets ALL of the following criteria:
    a. sagittal or coronal imbalance of at least 5 cm is present, as measured on long-plate, standing radiographs of the entire spine OR documented progression of deformity by at least 10 degrees as measured on consecutive radiographs over a one year period OR a fixed curve greater than 30 degrees in the coronal plane
    b. substantial functional limitation including severe back pain, difficulty ambulating, and decreased ability to perform activities of daily living
    c. failure of at least one year of nonoperative treatment
5. **Stenosis** in the lumbar spine (either central or foraminal), as an adjunct to decompression, that meet ANY of the following criteria: (*note: assumption is that the patient fulfills criteria for stenosis decompression as per Lumbar Stenosis Recommendation*)
    a. 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
    b. 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
    c. Cases in which decompression will likely result in iatrogenic instability, such as foraminal stenosis, during which greater than 50 percent of the facet joint will be removed to adequately decompress the exiting nerve root
    d. Adjacent level disease, e.g. stenosis that has developed above or below a previous fusion
    e. Recurrent stenosis, e.g. that which developed at a level that has been previously operated
6. **Disc herniations** in the lumbar spine, as an adjunct to disc excision, that meet ANY of the following criteria: (*note: assumption is that the patient fulfills criteria for discectomy as per Disc Herniation Recommendation*)
    a. Primary extraforaminal disc herniation is present at L5-S1, in which a far lateral approach is not feasible because of the presence of the iliac wings
    b. Primary foraminal disc herniation for which facet resection is necessary to retrieve the disc, which will result in iatrogenic instability
    c. Recurrent disc herniation

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d. Primary disc herniation in the lumbar spine that is at the level of the spinal cord (i.e. low lying conus medullaris)

7. **Synovial facet cysts** in the lumbar spine, as an adjunct to cyst excision

8. **Discogenic low back pain** secondary to a degenerated disc that meet ALL of the following criteria:
    a. Advanced single level disease noted on an MRI and plain radiographs of the lumbar spine, characterized by moderate to severe degeneration of the disc with Modic changes (defined as peridiscal bone signal above and below disc space in question) as compared to other normal or mildly degenerative levels (characterized by normal plain radiographic appearance and no or mild degeneration on MRI)
    b. Presence of symptoms for at least one year AND that are not responsive to multi-modal nonoperative treatment over that period that should at least include physical therapy/rehabilitation program but may also include (but not limited to) pain management, injections, cognitive behavioral therapy, and active exercise programs.
    c. Absence of active significant psychiatric disorders, such as major depression, requiring pharmaceutical treatment
    d. Absence of smoking for at least 3 months prior to surgery date
    e. Primary complaint of axial pain, with a possible secondary complaint of lower extremity pain
9. **Pseudarthrosis** in the lumbar spine that meet ALL the following criteria (a-d) OR demonstrate presence of a gross failure of the instrumentation (e.g. pedicle screw breakage, screw loosening, curve/correction decompensation)
    a. Mechanical low back pain that is approximately at the level of the pseudarthrosis, qualified as pain that can be somewhat positionally abated
    b. A period of time following the index surgery during which the patient had symptomatic relief
    c. Nonoperative care for at least 6 months
    d. CT or plain films that are highly suggestive of nonunion at a lumbar segment at which a fusion had been previous attempted. These criteria include:
        i. Lack of bridging bone
        ii. Dynamic motion noted on flexion-extension radiographs

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Lumbar fusion is **NOT** indicated in cases that do not fulfill the above criteria. Of note, lumbar fusion is not indicated in the following scenarios:

- **Disc herniations**:
  - as an adjunct to primary excision of a central or posterolateral disc herniation at any level in the absence of instability or spondylolisthesis
- **Stenosis:**
  - As an adjunct to primary decompression of central and/or lateral recess stenosis in the absence of instability, foraminal stenosis, spondylolisthesis
- **Discogenic low back pain:**
  - Any case that does not fulfill ALL of the above criteria
  - Presence of advanced multi-level degeneration (2 or more levels) on a preoperative MRI and plain radiographs
  - Significant psychiatric disorder
  - Smoking

Rationale for Coverage Recommendation

Lumbar fusion remains one of the most commonly performed procedures in spinal surgery. Despite pervasive negative attention in the lay media and many scientific publications (http://www.nytimes.com/2010/04/13/health/research/13proc.html , http://www.nytimes.com/2003/12/31/business/an-operation-to-ease-back-pain-bolsters-the-bottom-line-too.html), lumbar fusion continues to have a critical and important role in the treatment of a variety of spinal conditions. The proposed Coverage Recommendation (also known as the "Recommendation") 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 Recommendation 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 rationale for coverage of lumbar fusion for the treatment of spinal infections is based on what most practitioners would consider to be accepted practice patterns. The primary focus of treatment of a spinal infection is to either treat impending neurological deficit from a progressive deformity or expanding focus of infection. The latter can be manifest from an epidural abscess or an invasion of infected, necrotic, or pathologically fracture bone into the spinal canal or neural foramina. Instability remains judged on an individual case-by-case basis and can be evidenced by

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progressive deformity, bone loss, or involvement of a stabilizing structure such as a facet joint. Instability is a frequent by-product of surgical debridement or decompression, such as in cases in which an anterior corpectomy is performed in order to remove infected bone and disc material or access an epidural abscess. This can also be the case in which a posterior approach is used to access an abscess or infected disc or vertebral body (e.g. posterolateral approach). During this approach, extensive removal of the posterior elements, including bilateral facet joints, pedicles, and transverse processes, is effected in order to access the anterior elements. This would substantially destabilize the spine, thus necessitating instrumentation and fusion of the operated segments. Of note, there are no randomized controlled trials comparing operative to nonoperative intervention for spinal infections or comparing decompression versus decompression and fusion. The most likely reason for this is that most would consider such trials to be unethical in nature because of the established benefit of fusion in this patient population.

In item 2, the rationale for coverage of lumbar fusion for spinal tumors is again based on what most practitioners would consider to be accepted practice patterns. Of note, in distinction to some other policies that the Task Force has reviewed, this should not be limited to primary bone tumors. The removal of extradual soft-tissue tumors, such as might occur with metastatic disease or lymphoma that do not necessarily cause bone destruction will often require destabilizing approaches to the spine in order to safely access and remove the lesion. Thus, for a similar rationale as detailed above for item 1, the spine necessitates instrumentation and fusion to restore stability. Of note, there is a randomized controlled trial comparing operative to nonoperative treatment for the treatment of metastatic spinal cord compression, which has clearly shown an advantage for surgery in maintaining and restoring neurological function[1].

In item 3, the rationale for coverage for fusion for traumatic injuries of the lumbar spine is based on both high-level evidence, for injuries such as burst fractures of the thoracolumbar junction, as well lower level evidence and accepted practice patterns. The main indications for surgery after a traumatic injury to the lumbar spine are instability, which can be evidenced in a number of different manners, and neurological compression with or without a neurological deficit. A randomized controlled trial published by Wood et al[2] found equivalent treatment outcomes between surgery and bracing in patients with stable thoracolumbar burst fractures without neurological deficits. Excluding this precise injury, which represents only one of many types of injuries that can occur in the thoracolumbar spine, there are no prospective, randomized comparisons between operative and nonoperative treatment. The role of fusion and instrumentation for the treatment of unstable fractures, dislocations, fracture-dislocations, or purely ligamentous injuries is well-established

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among spine practitioners and will not likely be studied in the future by a randomized trial of operative and nonoperative treatment modalities.

In item 4, the rationale for coverage for lumbar fusion for the treatment of adult spinal deformities is based on the most current peer-reviewed evidence. In 2006, Schwab et al studied the disability in 947 patients with adult spinal deformity[3]. This group of highly experienced deformity surgeons utilized the following inclusion criteria that are relevant to the lumbar spine: sagittal or coronal imbalance of at least 5 cm, scoliotic curve of at least 30 degrees, lumbar kyphosis in more than 3 levels, and documented curve progression of 10 degrees. Among their study cohort, they found significant associations between various curve parameters and Oswestry Disability Index (ODI) scores as well as SRS-22 questionnaire scores. In 2005, Glassman et al, in a review of 298 patients, found that the coronal imbalance of greater than 4 cm and positive sagittal imbalance were the most reliable predictors of clinical symptoms[4]. The results of corrective surgery of deformity have similarly been most predicted by the degree of sagittal balance correction achieved (Mac-Thiong JM et al[5], Lafage et al[6]). With restoration of sagittal balance, health related quality of life outcome measures are improved. Of most importance, the Recommendation includes failure of at least one year of nonoperative treatment prior to surgery, as this is what most would consider a reasonable duration during which a patient should have at least some response nonsurgical modalities. That being stated, a study by Glassman et al published in 2010 found no significant improvements in HRQOL measures in a cohort of 123 patients who were treated with nonoperative care for spinal deformities[7].

In item 5, the rationale for fusion in patients who are to be operated on for lumbar stenosis is deeply rooted in the current evidence base. There are high-level data to support fusion following decompressive surgery in patients who have an underlying degenerative or isthmic spondylolisthesis. Herkowitz and Kurz found significantly better clinical (and radiographic) results when fusion was performed following laminectomy for spinal stenosis with degenerative spondylolisthesis[8]. The North American Spine Society Evidence-Based guidelines, in an extensive review of the literature, recommended fusion in the scenario as well. In an analysis of the SPORT data, Weinstein et al found substantially better outcomes in those patients treated with laminectomy and fusion compared to nonoperatively managed patients[9]. Regarding the radiographic definition of degenerative spondylolisthesis, there is no documented degree of slippage or absolute value in millimeters that has been reported in any of the above studies. Considering measurement errors previously documented, a minimum of 1 to 2 millimeters of

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translation as measured along the posterior vertebral bodies of the adjacent levels seems to be a reasonable threshold[10].

High-level evidence also exists regarding the role of fusion for adult isthmic spondylolisthesis, which usually presents with concomitant foraminal stenosis at the slipped level. In a prospective randomized controlled trial, Moller and Hedlund found significantly better clinical outcomes in patients who underwent surgery (that included fusion) than nonoperative care[11].

Concerning dynamic instability, there are currently no randomized controlled trials comparing operative to nonoperative treatment for dynamic instability of the lumbar spine. Patients who have dynamic instability, with or without the presence spinal stenosis on a static MRI (which, in the supine position, usually demonstrates the spine in a reduced position that will underestimate the degree of stenosis), if symptomatic, have a clear indication of an unstable spinal segment. To the Task Force's knowledge, there is not an accepted non-fusion method of surgical treating such a patient. Of note, there are currently no accepted radiographic criteria by which the change in alignment on flexion-extension views can be considered "instability". White and Panjabi have established criteria for clinical instability, with varying degrees of translational and angular deformity noted between two adjacent vertebrae. However, these criteria were developed in order to aid physicians in recognizing occult traumatic instability using plain radiographs, and were not intended to be used to determine clinical instability in the degenerative setting. As the measurement error of measurements made on flexion-extension views has been found to be between 0.7 and 1.6 degrees[10], the Task Force thought it would be reasonable to conclude that 2 mm of translational difference would reflect a real difference and be beyond the measurement error.

There are cases of lumbar stenosis that pose particular challenges. For cases in which there is severe foraminal stenosis, adequate decompression often can require aggressive resection one or both facet joints at a particular level. Removal of an entire facet joint, even unilaterally, is generally thought to be a destabilizing event in the lumbar spine[12]. While most cases of unilateral foraminal stenosis can be adequately decompressed with a non-destabilizing procedure, such as a foraminotomy, there are some cases in which the compression can be so severe and the orientation of the joint is such that achieving adequate decompression without producing iatrogenic instability can be difficult, if not dangerous to the underlying nerve root. This is a particular clinical scenario that would be exceedingly difficult to study that will likely not be addressed by a prospective, randomized trial (or other comparative trial for that matter). Recognizing this limitation in the evidence, that will likely persist, evidence-based medicine surgeons have made it clear that this

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should be reserved as a potential indication for fusion in the setting of stenosis without obvious signs of preoperative spondylolisthesis or instability[13].

Stenosis that redevelops at a level that has been previously operated on is a particular challenge to spinal practitioners. Patients who have failed nonoperative measures and are deemed operative candidates usually require a revision laminectomy/decompression. Almost implicitly, portions of the facet joint had been removed during the index procedure. Thus, a revision decompression often relies on resection of additional facet joint (or other posterior arch structures) in order to safely mobilize the dural or neural elements from the bony borders and adequately achieve decompression. In these cases, iatrogenic destabilization is a frequent occurrence and many times a planned portion of the surgery to enable safe execution. Thus, the rationale that fusion should be indicated in cases of revision decompression, even in the absence of clear signs of dynamic or static instability, is made based on technical considerations derived from surgical experience. As discussed above, this will likely not be studied in a prospective, randomized manner in the future. In an extensive review of the literature performed by one of the Task Force members, such a study could not be found[27].

The unique case of adjacent level stenosis is also worth discussing. The proposed mechanism by which adjacent level degeneration develops is rooted in the abnormal mobility and increased range of motion demands on the supra- or infrajacent level to a fusion. Thus, it would be difficult to rationalize performing a revision decompression at an adjacent level without extending the fusion to include the decompressed level. Again, there are no available randomized controlled trials comparing decompression at an adjacent level with or without fusion. However, in line with what most spine surgeons and the members of this Task Force believe to be reasonable and appropriate practice, such a study is unlikely to be performed. Evident of this fact, the literature concerning surgical treatment of adjacent level stenosis is replete with series of patients treated with revision decompression and extension of fusion[14].

As evidenced by **item 6**, there are limited circumstances in which a fusion would be indicated in the setting of performing a primary discectomy. In fact, there is literature to substantiate that routine inclusion of fusion in this setting does not improve outcomes[15, 16]. However, this does not account for a few particular situations. First, it is technically very difficult, if not impossible, to perform a far lateral approach at the L5-S1 level. Thus, for a primary surgery to remove an extraforaminal/far-lateral disc herniation at L5-S1, a fusion is often needed because the facet joint at L5-S1 must be completely removed in order to gain access to the disc herniation[17].

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Similarly, a foraminal disc herniation, which accounts for a very small percentage of all lumbar disc herniations, is often difficult to access through a standard laminotomy with medial facetectomy OR a far-lateral approach. In this unusual circumstance, performing a full facectomy to allow direct access to the disc herniation and visualization of the nerve root can afford the safest and most effective surgical treatment. While we are aware of case series that show that unilateral destabilization in the form of pars resection does not always result in instability requiring fusion[18], this technique for removal of intraforaminal disc herniations is not widely used or accepted.

Very rarely, a lumbar disc herniation at an upper level, such as L1-2 or L2-3, can occur in a patient with a low-lying spinal cord (i.e. conus medullaris). In effect, this is a case of spinal cord compression and should be treated more like a thoracic disc herniation. As the spinal cord cannot be retracted, removing the offending disc material can necessitate extensive resection of the posterior elements, such as is performed in a lateral extracavitary approach in the thoracic spine. In this rare case, fusion is a reasonable indication.

Finally, cases of recurrent disc herniation pose similar challenges as outlined above for recurrent stenosis. The presence of scar and previous facet joint resection, which is nearly omnipresent following an index discectomy, can risk iatrogenic destabilization of the facet joint with further resection for safe and adequate exposure. While there are no clear cut guidelines, many practitioners feel that a fusion is reasonably indicated following a second recurrence. However, the technical considerations discussed above are often present at the time of a revision discectomy for a first recurrence. Notwithstanding the presence of dynamic or static instability, fusion in the setting of a revision discectomy for a recurrent lumbar disc herniation is a reasonable practice. While data does not currently exist, the Task Force envisions a prospective randomized trial comparing revision discectomy with and without fusion in the future, which would offer useful data to this discussion.

In item 7, fusion in conjunction with facet joint excision is considered an indicated procedure. Recent evidence has suggested advantages with fusion compared to facet cyst excision alone. Xu et al reviewed the records of 167 patients who underwent surgery for a symptomatic facet cyst[19]. Seventy-four had cysts excision with fusion, while 90 underwent cyst excision without fusion. They found a significantly higher rate of recurrent cyst formation and recurrent back pain in the non-fusion patients. Notwithstanding these data, the Task Force recognizes that not all synovial facet cysts will require fusion. However, even in the absence of preoperative static or dynamic instability, fusion is reasonably indicated for the treatment of this clinical entity. Of note, there is a very high rate of adhesions between the facet cyst and the underlying dural sac, making complete excision of

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the cyst difficult without more extensive resection of the facet joint itself, which can lead to iatrogenic destabilization.

In item 8, there are specific criteria detailed to indicate lumbar fusion for the treatment of discogenic back pain, presumably from degenerative disease. The task force recognizes this is a highly controversial indication for fusion. The literature has conflicting evidence regarding the relative benefits of operative versus nonoperative treatment for this condition. In one randomized controlled trial, Brox et al found that fusion was no better than cognitive interventions and exercises at 2 years[20]. Notwithstanding the methodological critiques of the study, including the low patient numbers and a fusion method that most would consider to be less than ideal (i.e. it did not include interbody fusion), the group did find statistically better improvements in leg pain in the operative group compared to the nonoperative group, though this was not the primary focus of treatment. In a subsequent publication of the four year outcomes of this study, there were still no differences between the groups. Similar conclusions were drawn from a study by Fairbank et al, which also compared surgery to a cognitive program[21]. Of note, the surgical group included many non-fusion procedures, so it remains difficult to generalize the results to fusion. Contrastingly, Fritzell et al found statistically better outcomes with fusion compared to a relatively unstructured nonoperative treatment program, the latter being the main focus of criticism[22]. What is lacking from all of these studies were clear-cut radiographic criteria, barring the requirement of having so-called spondylosis. The Task Force has reviewed other nonrandomized studies that have indicated better outcomes when more strict radiographic and patient-centered inclusion criteria are used. In a prospective study commonly cited as evidence against fusion, Parker et al documented poor overall results in a group of so-called highly selected patients with discogenic low back pain (evaluated by MRI and discography), finding only 56% of patients being extremely satisfied with surgery[23]. However, if workman compensation cases are excluded, 90% of patients were extremely satisfied with the procedure. In a retrospective study of similarly highly select patients, Moore et al found that 87 percent of patient improved after an anterior-posterior fusion procedure for single level discogenic low back pain[24].

In reviewing the various randomized controlled trials comparing fusion to artificial disc replacement that have demonstrated equivalency between the two procedures, it becomes apparent that, in a select group of patients with strict radiographic and clinical inclusion criteria, fusion for discogenic low back pain can be a moderately effective procedure. Based on analysis of this breadth of literature, the Task Force developed a list of strict and rigorous criteria for fusion in this patient population. Based on the current level of evidence, as well as reasonable clinical judgment, only

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single level fusions for isolated single level degenerative disease noted on an MRI (with associated Modic changes) in non-smoking patients without significant psychiatric disorder would be indicated after at least one year of failure of nonoperative treatment.

In item 9, a number of studies were reviewed that have documented acceptable outcomes from repair (i.e. redo fusion) of a pseudarthrosis in the lumbar spine. In general, the studies demonstrate in an appropriately selected patient who has failed nonoperative treatment, that a revision surgery for pseudarthrosis repair can decrease symptoms and improve quality of life. Adogwa et al (2013), in a review of 17 patients from an institutional database, found that the VAS back pain and ODI scores significantly improved with revision surgery for pseudarthrosis at 2 years follow-up[29]. The diagnostic criteria this group used for pseudarthrosis were lack bridging bone across motions segments (on CT or plain films) or pedicle screw halos and motion on dynamic radiographs, corresponding mechanical low back pain, and prior attempted fusion at the level. At least 6 months of nonoperative care was required prior to surgery. In another study from the same group, Adogwa et al in 2011 reported the outcomes of a larger cohort of 47 patients who underwent pseudarthrosis repair in the lumbar spine[28]. The investigators reported significant improvements in VAS back pain, and SF-12 physical health scores at 2 years follow-up, while Zung Depression Scale scores and SF-12 mental component scores were not significantly improved. The inclusion and diagnostic criteria were the same as that in the 2013 study, with a minimum of 6 months of nonoperative care required prior to revision surgery. In a study specific to pseudarthrosis repair in 19 patients who previously underwent a stand-alone PLIF with a metallic cage, Cassinelli et al reported a 94% solid fusion rate and improvement in seven of eight of the SF-36 subcategories, though significant in only two subcategories[25]. Importantly, ODI scores were not significantly improved. This group did not clearly specify the preoperative criteria for pseudarthrosis. The range of time between initial PLIF and revision surgery was 9 months to 40 months. Other groups have reported the outcomes of pseudarthrosis repair following surgery adult deformity surgery, Pateder et al documented a 90 percent fusion rate with redo fusions for adult scoliosis with 80 percent of patients reporting that they would have the surgery again[26]. Harimaya et al, in a series of 33 patients who underwent revision surgery for failed lumbosacral fixation for adult deformity, highlighted the importance of strong caudal fixation, such as iliac screws, to avoid pseudarthrosis[30]. In this case, the diagnosis of pseudarthrosis is heralded by curve/correction decompensation and hardware breakage or pull-out, which may obviate a period of nonoperative care prior to considering revision surgery.

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