



December 15, 2010

Don W. Bradley, M.D.
Senior Vice President, Healthcare & Chief Medical Officer
Blue Cross and Blue Shield of North Carolina
5901 Chapel Hill Road
Durham, NC 27707

Subject: BlueCross BlueShield of North Carolina Lumbar Spine Fusion Surgery "Notification"

Dear Dr. Bradley:

The American Association of Neurological Surgeons (AANS), the American Association of Orthopaedic Surgeons (AAOS), the Congress of Neurological Surgeons (CNS), the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves, the International Society for the Advancement of Spine Surgery (ISASS), the North American Spine Society (NASS), the North Carolina Neurosurgical Society (NCNS), the Pediatric Orthopaedic Society of North America (POSNA) and the Scoliosis Research Society (SRS) would like to thank BlueCross and BlueShield of North Carolina (BCBS of NC) for the opportunity to provide comments on the draft Corporate Medical Policy pertaining to Lumbar Spine Fusion Surgery, with a policy effect date of January 1, 2011. As clinicians specializing in the care of spinal disorders, we understand the concern regarding the over utilization of lumbar fusions in the hands of certain individual practitioners, which becomes the impetus for such policy revisions. We applaud the goal of improving patient care through the application of scientifically grounded therapies, but have concerns regarding the criteria and guidelines for which BCBS of NC will provide coverage for lumbar spinal fusion. We therefore wish to offer suggestions to assist BCBS of NC in achieving its end goal of providing appropriate coverage for those patients who will benefit from lumbar spinal fusion.

The introductory paragraph of this policy suggests that lumbar spinal fusion is a procedure to treat low back pain. Although patients may have the symptoms of low back pain, most spinal fusion surgery is performed for a variety of diagnoses associated with either gross or micro-radiological instability due to an underlying disease process, the effects of decompression, or joint dysfunction. The list that is provided in the policy grouped patients with these diagnoses, who have a high probability of clinical success with fusion, with a group of patients with degenerative lumbar disc disease in whom surgical outcomes are less predictable. We recommend editing the last introductory paragraph (page 2, line 5) to replace the phrase "degenerative disc disease" with "disc herniation" when discussing diseases that respond well to surgical decompressive procedures alone. The term degenerative disc disease is quite broad and encompasses many pathologies, including those listed below, which could be indications for lumbar spine fusion as a treatment option.

1. Tran de QH, Duong S, Finlayson RJ. Lumbar spinal stenosis: a brief review of the nonsurgical management. *Can J Anaesth.* 2010 Jul;57(7):694-703. Epub 2010 Apr 29.

Section: "When Lumbar Spine Fusion Surgery is covered"

We agree with the coverage for "spinal repair surgery for dislocation, abscess or tumor". However, we request expansion of the coverage of fusion for not only "abscess", but also for other spinal infections. Spinal discitis and osteomyelitis often require debridement and can be a cause of lumbar spine instability with potential for involvement of the cauda equina, nerve roots, and lumbosacral plexus. Discitis, especially in patients who are immunocompromised, may require operative debridement, even when a spinal abscess is not present. Cases of fungal discitis require operative therapy, but seldom present with lumbar epidural or paraspinal abscesses. Patients on hemodialysis often require operative treatment for spinal infection, due to the difficulty of eradicating these infections with antibiotics alone. Inability to achieve appropriate microbiological identification of an offending organism may mandate operative exploration and debridement.

1. Priest DH, Peacock JE Jr. Hematogenous vertebral osteomyelitis due to *Staphylococcus aureus* in the adult: Clinical features and therapeutic outcomes. *South Med J*: 98: 854-862, 2005.

We agree with the coverage for lumbar spinal stenosis associated with spondylolisthesis in patients presenting with neurogenic claudication or radicular pain. This would encompass the majority of the patients who are symptomatic from central and lateral recess stenosis. While instability is not typically introduced with routine decompression for central lumbar or lateral recess stenosis, decompression for severe foraminal stenosis or in the presence of severely diseased facet joints (e.g., "kissing facets") sometimes involves bilateral extensive facetectomies. Removal of a substantial portion of the facet joints in order to afford adequate decompression can create incompetence of the vertebral motion segment. In such situations, fusion is appropriately performed in order to avoid postoperative instability and thus we would recommend iatrogenic instability as a covered procedure. In addition, we would recommend the addition of radiculopathy to the list of progressive symptoms (which currently includes neurogenic claudication and cauda equine syndrome) as an indication for fusion. Patients with spinal stenosis can have profound and progressive neurologic deficits that may only present with a radicular distribution (e.g., foot drop), which would not satisfy the definition of cauda equina syndrome or neurogenic claudication.

1. Resnick, et. al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 9: fusion in patients with stenosis and spondylolisthesis. *J Neurosurg: Spine* 2:679-685, 2005.

We agree that surgical treatment of adult degenerative scoliosis patients should be patient specific, with an additional extensive trial of conservative therapy prior to consideration of operative options. However, these patients may present with neurologic deficits in addition to radicular or axial pain. Development of chronic neurological deficits in this patient population may produce permanent functional deficits. The present recommendations state that adult patients with degenerative scoliosis who present with loss of function require 3 months of conservative therapy prior to operative intervention. While unusual, a patient with degenerative lumbar deformity may present with acute lower extremity weakness, most commonly a foot drop, secondary to severe foraminal stenosis. Delay of decompression in this patient population may yield a permanent functional impairment. The most recent review notes superior patient satisfaction and good clinical outcomes in surgical stabilization of these patients. Hence, we would request that functional loss in a patient population with a degenerative deformity that warrants fusion not be mandated to complete 3 months of conservative therapy prior to consideration of operative intervention. As a point of clarification, such patients may be more appropriately indicated as "spinal stenosis" patients and thus have treatment guided by point 4 b. Patients with lumbar sagittal imbalance may present with severe axial discomfort, but possibly not with neurologic impairment or fixed neurological deficit. The definition of "impairment" in these patients will be crucial: Is limitation in daily activities or reduction in ambulatory tolerance adequate to merit operative intervention? In this subset of patients, we emphasize as clinicians that surgery is a quality of life decision, with choice of surgery made after conservative therapies have been exhausted and when the degree of functional impairment

produced by the correlative deformity is significant enough to merit operative therapy. Hence, in present practice, these clinical decisions rest upon extensive discussion of different treatment options with each patient, with therapy individualized accordingly. We would hope that coverage decisions would respect the informed treatment decisions made by these patients.

1. Transfeldt EE, Topp R, Mehbod AA, Winter RB. Surgical outcomes of decompression, decompression with limited fusion, and decompression with full curve fusion for degenerative scoliosis with radiculopathy. 2010 Spine 35: 1872-1875.
2. Kim YJ, Bridwell KH, Lende LG, Cheh G, Baldus C. Results of lumbar pedicle subtraction osteotomies for fixed sagittal imbalance: A minimum 5-year follow-up study. 2007 Spine 32: 2189-2197.

We agree that patients with isthmic spondylolisthesis who are unresponsive to conservative nonsurgical care are candidates for lumbar spinal fusion. We would like to clarify that the policy's denoting type II spondylolisthesis is referring to the Wiltse et al classification system, which describes this type as isthmic in nature, and not the Meyerding classification, which defines a grade II slip as that which is 25 percent to 50 percent slipped. If the latter was the intent, the criterion of having a Meyerding grade II spondylolisthesis seems to be overly restrictive. The majority of symptomatic patients with isthmic spondylolisthesis have no more than a 25 percent slippage of the vertebrae, which would be defined as a grade I slip according to the Meyerding grading system. The best available randomized control trial of comparative effectiveness between spinal fusion and nonoperative conservative care in this patient population has demonstrated superior results with surgery. If the former was the intent, then we would question why dysplastic spondylolisthesis (Wiltse et al Type I) patients are not considered appropriate candidates for fusion surgery. Though not as common as isthmic spondylolisthesis, the clinical presentation and treatment recommendations of this patient population is similar to those for isthmic spondylolisthesis. Thus, we would ask that Type I (dysplastic) spondylolisthesis be added to the coverage list. On a separate note, documentation of gross radiographic "progression" requires years in many, if not most, patients and may not always be available. Many asymptomatic patients do not have spinal x-rays, and many individuals with acute onset of symptoms will not have x-rays obtained until they fail conservative management with their primary care physician. As such, despite months of symptoms, they will not have had prior spinal x-rays prior to seeing a surgeon identifying a progression of slippage as a consideration for spine surgery. The mandate for radiographic progression should be excluded.

1. Möller H, Hedlund R. Surgery versus conservative management in adult isthmic spondylolisthesis--a prospective randomized study: part 1. Spine (Phila Pa 1976). 2000 Jul 1;25(13):1711-5.

We agree with supporting coverage of spinal fusion for patients with recurrent, same level, disc herniations. Current literature and practice would indicate a revision discectomy as the preferred surgical option in those with only nerve root symptoms with radicular pain, weakness, or numbness due to a recurrent disc herniation. However, we recommend removing the criteria of "at least 6 months after previous disk surgery" as the timing of a recurrent disc herniation may occur well before this time point. For instance, an early recurrence may occur at 1-2 months from index surgery. According to the current policy, this patient would have to undergo six months of non-operative treatment before a revision discectomy and fusion could be approved. If for instance, this was a second or third recurrence and fusion was deemed the most appropriate definitive treatment, it would seem that the proposed policy would not provide coverage for what is arguably the most appropriate treatment (i.e., revision discectomy and fusion) until six months of nonoperative care had been delivered. This seems to be an unjustifiably long period of time to delay discectomy, particular considering the most recent literature regarding the influence of timing of discectomy and outcomes (SPORT Trial Report, AAOS Annual Meeting, 2010). Thus, we would propose that the number of recurrences be part of the appropriateness criteria. Similarly, we would also recommend the deletion of "unresponsive to at least 3 months of conservative nonsurgical care" as there are many cases of significant radiculopathy or even cauda equina syndrome

in which the patient's progressive symptoms should not wait 3 months for their definitive surgical management. The timing of the appropriate surgery should be determined by clinical criteria and not by a surrogate measure such as time after onset of symptoms.

1. Resnick, et. al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 8: lumbar fusion for disc herniation and radiculopathy. J Neurosurg: Spine 2:673–678, 2005.

Section: "When Lumbar Spine Fusion Surgery is not covered"

Although not routine, we do not agree that lumbar fusion surgery should unilaterally not be covered for disc herniation, initial discectomy, or initial laminectomy for neural structure decompression. Though rare, caveats to this "rule" should be considered. A discectomy for a foraminal herniation, for example, can include resection of a large portion of facet joint that can lead to iatrogenic instability (Lee et al, Spine, 2004). While iatrogenic instability can usually be avoided during central or lateral recess stenosis decompression, adequate decompression of severe foraminal stenosis can involve resection of a large portion of a facet joint. In such situations, fusion to stabilize the motion segment would be reasonably indicated in select cases.

1. Resnick, et. al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 8: lumbar fusion for disc herniation and radiculopathy. J Neurosurg: Spine 2:673–678, 2005.
2. Lee KK, Teo EC, Qiu TX, Yank K. Effect of facetectomy on lumbar spinal stability under sagittal plane loadings. Spine (Phila Pa 1976). 2004 Aug 1; 29(15):1624-31.

We acknowledge that the indications for lumbar fusion surgery for "degenerative disk disease" remain controversial. Degenerative disc disease is an often misused term as these degenerative disc changes occur in the normal human spine as a result of aging. It is a broad term that encompasses problems for which no reasonable spine surgeon would recommend a fusion (e.g. multilevel degeneration with nonspecific, nonlocalized back pain) as well as those for which many reasonable spinal surgeons would recommend fusion in specific circumstances (i.e. localized back pain, unresponsive to exhaustive nonoperative care, that is reasonably correlated to a single, highly degenerated motion segment). With the physician doing his or her due diligence, severe intractable symptoms can be reasonably attributed to the specific motion segment in question by history, physical examination, and sometimes provocative discography. In such a scenario, it would be reasonable to consider a lumbar fusion for so-called degenerative disc disease. We feel strongly that an intensive course of physical therapy and cognitive therapy is recommended as a treatment option for patients with low-back pain in whom conventional medical management has failed. We feel strongly that the scope of patients with low back pain from degenerative disease without neurological compression, neurological symptoms, or mechanical instability should be much more limited than it has in the past. However, we feel that to completely omit this as a covered procedure under any circumstance is overly restrictive. Thus, we offer the following criteria for lumbar fusion in a patient with low back pain and degenerative disc disease: single or two level disc degeneration, inflammatory endplate changes (i.e., Modic changes), moderate to severe disc space collapse, absence of significant psychological distress or psychological comorbidities (e.g. depression, somatization disorder), absence of litigation or compensation issues, and failure to respond to at least 1 year of nonoperative care that includes physical and cognitive therapy.

1. Resnick, et. al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 7: intractable low-back pain without stenosis or spondylolisthesis. J Neurosurg: Spine 2:670–672, 2005.

In areas of less well defined conditions or more controversial treatments, we suggest coverage review with the medical director. We all understand that situations will arise in which the patient does not neatly fit the criteria and we believe the policy will be strengthened with the inclusion of a statement that

accommodates coverage consideration outside of the clearer clinical applications of fusion with case by case review.

Again, thank you for this opportunity to comment and assist BCBS of NC in developing an appropriate coverage policy that will allow us to provide quality spine care for our patients. We believe that our suggestions -- which will affect a limited number of patients who will substantially benefit from improved quality of life -- will improve the current proposed Corporate Medical Policy pertaining to Lumbar Spine Fusion Surgery and are critical to ensuring that these individuals have the full range of treatment options. We look forward to seeing a revision to your policy prior to its implementation. We would be pleased to discuss this further with you in person or on a telephone conference call before the policy is finalized and implemented.

If you have any questions, please feel free to contact Joseph Cheng, MD, AANS/CNS Coding and Reimbursement Committee at joseph.cheng@vanderbilt.edu or Cathy Hill, Senior Manager, Regulatory Affairs AANS/CNS at chill@neurosurgery.org.

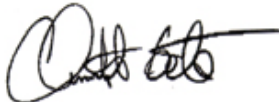
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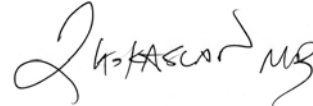
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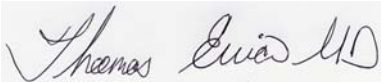
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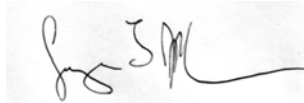
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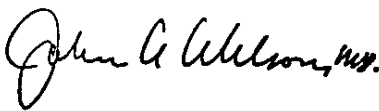
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