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NEUROLOGICAL SURGEONS

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June 1, 2012

H. Scott Sarran MD  
Chief Medical Officer and Vice President  
Blue Cross and Blue Shield of Illinois  
300 East Randolph Street  
Chicago, Illinois 60601-5099

Subject: BlueCross BlueShield of Illinois Lumbar Spine Fusion Policy

Dear Dr. Sarran:

The American Association of Neurological Surgeons (AANS), the American Association of Orthopaedic Surgeons (AAOS), the Congress of Neurological Surgeons (CNS), and the AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves would like to thank BlueCross and BlueShield of Illinois (BCBS of Ill.) for the opportunity to provide comments on the draft Corporate Medical Policy pertaining to Lumbar Spine Fusion Surgery. 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 Ill will provide coverage for lumbar spinal fusion. We therefore wish to offer suggestions to assist BCBS of Ill in achieving its end goal of providing appropriate coverage for those patients who will benefit from lumbar spinal fusion.

### ***Proposed Criteria for Coverage***

Regarding section 8, we agree that surgical treatment of adult degenerative scoliosis patients should be patient specific, with an additional extensive trial of nonoperative therapy prior to consideration of operative options. However, these patients may present with neurologic deficits in addition to radicular or axial pain (Ref 1). Development of chronic neurological deficits in this patient population may produce permanent functional deficits. The present recommendations state that adult patients with degenerative scoliosis require 3 months of conservative therapy prior to operative intervention. While unusual, 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 intervention not be mandated to complete 3 months of nonoperative therapy prior to consideration of operative intervention. Recent research has demonstrated that there is minimal benefit to nonoperative management of patients with adult deformity (Ref 2). In this study, patients who used nonoperative resources had no significant change in any of the health related quality of life outcome parameters. Hence we feel that completion of three months of non-operative management should not be required.

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. Glassman SD, Carreon LY, Shaffrey CI, Polly DW, Ondra SL, Berven SH, Bridwell KH. The costs and benefits of nonoperative management for adult scoliosis. Spine (Phila Pa 1976). 2010 Mar 1;35(5):578-82.

Regarding section 10, we agree that patients may benefit from lumbar fusion surgery with osteotomy in cases of iatrogenic or degenerative flat back syndrome with sagittal imbalance. However, we also would like to remind you that surgeons can often achieve satisfactory sagittal imbalance correction without osteotomy through the use of multiple interbody grafts (Ref1), and through the use of instrumentation in patients who have partially reducible deformities. Performing osteotomies has the potential to increase risk to a procedure (Ref 2) and should mainly be considered in patients with fixed sagittal plane deformity. We therefore feel that section 10 should be changed to, "iatrogenic or degenerative flat back syndrome with significant sagittal imbalance, when performed with spinal osteotomy or multiple interbody grafts."

1. Jagannathan J, Sansur CA, Oskouian RJ Jr, Fu KM, Shaffrey CI. Radiographic restoration of lumbar alignment after transforaminal lumbar interbody fusion. Neurosurgery. 2009 May;64(5):955-63; discussion 963-4.
2. Smith JS, Sansur CA, Donaldson WF 3rd, Perra JH, Mudiyan R, Choma TJ, Zeller RD, Knapp DR Jr, Noordeen HH, Berven SH, Goytan MJ, Boachie-Adjei O, Shaffrey CI. Short-term morbidity and mortality associated with correction of thoracolumbar fixed sagittal plane deformity: a report from the Scoliosis Research Society Morbidity and Mortality Committee. Spine (Phila Pa 1976). 2011 May 20;36(12):958-64.

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.

### ***Proposed Criteria for Non-Coverage***

Although not routine, we disagree 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 often a 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 ostensible 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. The situation will undoubtedly arise where the patient does not precisely fit the criteria. Under these circumstances, 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 Illinois in developing an appropriate coverage policy that will allow us to provide quality spine care for our patients. We believe the suggestions contained herein will substantially benefit a limited number of patients and, on a larger scale, will improve the current proposed Corporate Medical Policy pertaining to Lumbar Spine Fusion Surgery. Incorporating the above revisions is critical to ensuring that these individuals have the full range of treatment options.

We also 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 us.

Sincerely,

A handwritten signature in black ink, appearing to read "Joseph Cheng". The signature is fluid and cursive, with a large loop at the end.

Joseph Cheng, MD, Chair  
AANS/CNS Joint Section Joint Section on Disorders of the Spine and Peripheral Nerves  
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