March 8, 2011

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Subject: Clinical Policy Bulletin: Spinal Surgery: Laminectomy and Fusion Number: 0743

Dear Dr. Reisman:

The American Association of Neurological Surgeons (AANS), Congress of Neurological Surgeons (CNS), AANS/CNS Joint Section on Disorders of the Spine and Peripheral Nerves, American Academy of Orthopaedic Surgeons, AOSpine North America, International Society for the Advancement of Spine Surgery and North American Spine Society would like to thank the you and Aetna for the opportunity to provide comments on your "Clinical Policy Bulletin: Spinal Surgery: Laminectomy and Fusion" (policy #743), which was recently reviewed and updated December 14, 2010 and posted onto your web site (http://www.aetna.com/cpb/medical/data/700_799/0743.html). As surgeons, we applaud the insightful review of the recent literature on spinal surgery procedures in the quest to improve patient care through the application of scientifically grounded therapies. However, we do have some concerns regarding the criteria and guidelines for which Aetna will provide coverage for Lumbar Spinal Fusions, and believe that your coverage policy will negatively affect patient access to this treatment when needed and medically indicated. We therefore ask that Aetna consider the following issues and modify its policy to achieve our shared goal of optimal patient care.

Our comments reflect the structure of the Clinical Policy Bulletin:

I. Aetna considers lumbar laminectomy medically necessary for individuals with a herniated disc when* all *of the following criteria are met:

We are concerned about the need to meet all relevant criteria offered in the policy bulletin as this may generate denials of coverage in patients where operative intervention is appropriate, requiring appeals that may delay appropriate patient care.

A. All other sources of pain have been ruled out; and

We would ask that this phrase be edited to "All other ***reasonable*** sources of pain have been ruled out". The current wording may promote additional testing to be ordered on patients who otherwise may have relatively clear clinical presentations. We are concerned that surgeons

may misinterpret this policy statement as a need to rule out all possible different diagnoses, such as piriformis syndrome, rather than what is considered reasonable in the course of an accepted standard patient evaluation.

C. Member has failed at least 6 weeks of conservative therapy (see background section); and

We would request that an allowance for early surgery for intractable pain be allowed, by adding "*or suffers intractable, incapacitating pain*." While we agree with the general tenet that the majority of lumbar disc herniations will respond to conservative management and will not require operative intervention, some patients may have severe, unremitting pain that requires more acute treatment. Incapacitating pain is, in our opinion, an indication for early operative intervention.

E. Physical findings of nerve root tension are present (e.g., positive straight leg raising); and

We request that this requirement be removed from the criteria. The straight leg raise (Lasègue's sign) is primarily for nerve root entrapment at L5 and S1, and therefore not all patients with significant lumbar radiculopathy will have a positive straight leg raise leading to a sensitivity of 91% and a specificity of 26%[1]. In addition, these examinations have not been found to correlate with radiographic findings of lumbar root compromise[2].

F. Presence of neurological abnormalities (e.g., reflex change, sensory loss, weakness) persist on examination and correspond to the specific affected nerve root.

We would ask that instead of "and" preceding this condition, that it be changed to **"or"**. While the preceding criteria, including 6 weeks of conservative therapy, appear sound in a patient who needs predominantly pain management, they would not be in a patient with rapid loss of function such a foot drop or urinary dysfunction without a cauda equina syndrome diagnosed. These neurological abnormalities would indicate urgency for a surgical decompression and should not be co-opted by the preceding criteria or the need to wait for fulminant cauda equine syndrome.

II. Aetna considers cervical laminectomy (may be combined with an anterior approach) medically necessary for individuals with a herniated disc when all of the following criteria are met:

Similar to the above concerns, the requirement that <u>all</u> criteria be met may prove difficult. Not all patients present with all described findings of cervical spinal cord or nerve root compromise.

A. All other sources of pain have been ruled out; and

Here again we would ask that this phrase be edited to "all other ***reasonable*** sources of pain have been ruled out". The current wording may promote additional testing to be ordered on patients who otherwise may have relatively clear clinical presentations. Elimination of "all other sources" of pain will require that patients undergoing treatment for cervical pathology be evaluated for diverse pathology such as Parsonage-Turner syndrome to Dejerine-Roussy syndrome prior to offering surgical treatment, rather than what is considered reasonable in the course of an accepted standard patient evaluation.

B. History of neck pain with radicular pain to the upper extremity, weakness, and sensory disturbance; and

Neck and radicular pain may not be present in all patients. Many patients may present with radiculopathy without neck pain. Patients may present with motor loss and not have sensory

changes or pain. Classically, radicular loss involving the fifth cervical nerve root may produce significant weakness with minimal pain and no sensory changes[3]. We would suggest modification of the policy to be "**neck or cervico-brachial pain with findings of weakness, myelopathy, or sensory deficit**".

C. Imaging studies (e.g., CT or MRI) indicate disc herniation at the level corresponding with the clinical findings; and

Not all patients presenting with significant spinal cord or nerve root compromise have cervical disc herniations. Patients may present with osteophytic spurring or ligamentous hypertrophy producing anterior, posterior, or combined canal compromise. We would suggest cervical disc herniation be replaced by **"compression of the spinal cord or nerve root(s)"**.

IV. Aetna considers cervical, lumbar, or thoracic laminectomy medically necessary for any of the following:

While we agree with the indications for spinal fracture or dislocation, infection, and tumor; there are other pathologies that require laminectomy. These include deep extradural masses such as epidural hematomas, either post-traumatic or spontaneous, and synovial cysts, or intradural mass lesions such as arachnoid cysts with neural element compromise. These are not neoplasms, infection, or fractures, and so would not be covered under the current policy based upon criteria noted in Sections I, II, and IV. In addition, central cord syndrome may be present in patients with static central canal compromise, and without a cervical fracture or dislocation, with profound neurological deficits. Our interpretation of the current Aetna policy is that these cases would not be covered[4]. We therefore recommend amending this section to **"Any mass lesion with significant spinal cord or nerve root compression such as spinal fracture or dislocation, hematoma, infection, cysts, and tumor"**.

VI. Aetna considers lumbar spinal fusion experimental and investigational for degenerative disc disease and all other indications not listed above as medically necessary because of insufficient evidence of its effectiveness for these indications.

We do not believe that the current policy adequately summarizes the medical literature with regard to surgery for lumbar degenerative disc disease (DDD). While the literature on surgical treatment of lumbar DDD remains controversial, the highest quality prospective and controlled randomized study of surgery for lumbar DDD showed clear benefits in operatively treated patients[5]. Other studies demonstrate clinical efficacy in surgical treatment of this patient population[6-8]. Anterior lumbar interbody fusion was accepted as a standard of care for treatment of lumbar DDD by the US Food and Drug Administration in evaluation of the CHARITÉ™ lumbar arthroplasty device, a procedure approved for coverage by Aetna policy.

Background

We agree with the general tenets of conservative treatment of low back pain (LBP) noted in the Background portion of the Discussion. LBP is, for the majority of patients, a self-limited phenomena that does not require radiographic evaluation or operative intervention[9, 10]. We agree with the general recommendations that conservative treatments be completed prior to consideration of operative therapy. Consideration of operative intervention should be reserved for patients who have failed a thorough, appropriate, and lengthy course of conservative treatments. As reviewed in the Spine Patient Outcomes Research Trial (SPORT), there are various options for conservative intervention available to practitioners. There are no clear standards as to what constitutes an appropriate course of conservative therapy, although a general rule of six to twelve weeks of such therapy is standard[11-13].

We disagree with the statement from the Agency for Healthcare Research and Quality assessment, noting that "the evidence for lumbar spinal fusion does not conclusively demonstrate short-term or long-term benefits compared with non-surgical treatment, especially when considering patients over 65 years of age, for degenerative disc disease; for spondylolisthesis, considerable uncertainty exists due to lack of data, particularly for older patients." The more recently published SPORT data assessing outcomes in decompression and stabilization in patients with degenerative spondylolisthesis, as reviewed elsewhere in your text, clearly demonstrate superiority of operative stabilization compared with conservative care with four-year follow-up[14]. Presence of a spondylolisthesis correlated strongly with better outcomes in operatively treated patients[15].

The American Pain Society Clinical Practice guidelines summarized in the policy rely upon literature reviews completed by Chou et al[16]. In assessing surgery for LBP with lumbar degenerative disease, reviewing four trials comparing operative and non-operative therapy, the report notes no clear guidelines can be drawn from the extant literature. It is of note that only four articles were considered in this review.

The most recent review article summarized six large, rigorously conducted, randomized comparative trials on fusion at 1 or 2 levels for pure DDD. The authors concluded that “fusion appears superior to unstructured nonoperative treatment, similar to structured nonoperative treatment, and similar to short-term results of artificial disc replacement”. The authors note that intensive structured nonoperative treatment is generally not available today in the USA and that surgical fusion and intensive structured nonoperative treatment are not mutually exclusive and together might hypothetically have a synergistic effect[17]. A recent randomized controlled trial appears to support this idea[18].

We appreciate the reporting of Cochrane and other literature reviews explicating previous trials of operative and nonoperative treatment of lumbar disc prolapse. The significant design weaknesses inherent to the SPORT and other trials illustrate the difficulty in completing prospective analyses of spine surgery patients[19]. We would concur with the results of the Cochrane assessment that the majority of lumbar herniated discs will improve without surgical treatment. When conservative treatment fails, operative intervention is supported by the literature[12, 13].

Chronic axial back pain in patients previously treated with lumbar discectomy poses significant clinical challenges. It is unclear whether persistent back pain after lumbar discectomy and idiopathic LBP without previous intervention will respond similarly to operative intervention. In this difficult patient population, a prospective study completed by Brox et al. showed poor outcomes in both operative and non-operatively treated patients[20].

The policy statement briefly reviews the guidelines prepared by the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS). The document does not report, however, the primary conclusion of the individual guidelines relating to surgery for intractable LBP with or without stenosis and the applicability of certain provocative testing. Based upon review of the literature, the AANS/CNS guidelines recommended that lumbar fusion be considered as a treatment for “carefully selected patients with disabling low-back pain due to one- or two-level degenerative disease without stenosis or spondylolisthesis” [21]. The same guidelines note that lumbar discography may offer valuable information in the evaluation of patients with intractable LBP and abnormalities on MRI imaging[22].

We concur with the review of the SPORT outcomes provided by the text[12, 13]. The Vokshoor report, noted next in the policy statement, is a non-peer reviewed assessment published upon the eMedicine website. While we appreciate the comments offered, it is of note that Aetna’s conclusions are not supported by similar evidence as the SPORT datasets[23]. Similarly, the citation from

Wheeless et al. refers to an online orthopedic surgery textbook, and refers to an online chapter with a single citation. It is not clear that this provides adequate substantiation for clinical practice guidelines[24].

The policy notes a review by Maghout Juratli et al., noting changes in operative techniques in a Washington State workman's compensation model for lumbar spine surgery. This study, while large, suffers from being a retrospective, population based review, and hence is low quality data and should not be utilized to formulate treatment guidelines. Similarly, the study suffers from concentrating solely upon Workman's Compensation patients exposed to the unique disability laws of said state, perhaps not a representative sample of the United States population[25]. The Washington State Health Technology Assessment Program, reviewed at length in the policy, reviewed four randomized controlled trials and drew conclusions different than the AANS/CNS guidelines group[26]. The primary conclusion of the text that lumbar fusion provided greater pain relief and disability improvement than nonoperative care and that t that the present lumbar fusion literature for axial LBP is of poor quality.

There are substantial differences between the text presented in Aetna's policy regarding the Washington State Department of Labor and Industries' recommendations and the recommendations present in the most recent iteration of this document, effective November 1, 2009. The new recommendations note that lumbar fusion should be considered in patients who have not had previous surgery if one or more of the follow criteria are met:

1. The patient has mechanical LBP with instability, defined as anterior/posterior translation of 4 mm at L3-4 or L4-5 or 5 mm at L5-S1, or 11 degrees or greater of endplate angular change at a single level.

2. At least a grade 2 spondylolisthesis with
   a. Neurogenic claudication
   b. Radiculopathy, correlated with MRI or CT
   c. Instability, as defined in criteria #1

In patients where previous surgery has been completed and conservative therapy has not relieved residual or recurrent symptoms, surgical stabilization is considered when:

1. A patient has mechanical LBP with instability, or
2. A patient has mechanical LBP with a deformity, or
3. Signs of neurogenic claudication or radiculopathy, or
4. Signs of post-laminectomy structural facet compromise

The guidelines offer specific requirements for patients undergoing lumbar stabilization for lumbar degenerative disease. These include completing a structured intensive multidisciplinary program for chronic pain management. These recommendations are clearly distinct from the review offered in the text of the Aetna policy[27].

The growth trends of lumbar instrumented fusion in the United States have been well described[28]. The clinical impact of this growth is not clear. Martin et al. attempted to correlate this increased cost with lack of improvement in clinical status of patients with low back and neck pathology, indirectly questioning the value of technological development in spine procedures[29]. There are numerous significant problems in Martin et al.'s report:

1. The change in expenditures reported did not achieve statistical significance. Spine patients spent 72% more than non-spine patients in 1997 and 73% more in 2005 (p=.07). The rate of

medical inflation seems to be constant. This is not emphasized, with the authors instead emphasizing the statistically insignificant change in costs.

2. Many more patients with spinal cord injuries are included in the later sample (0.1% in 1997 versus 1.8% of the patient cohort in 2005). This might imply better survival of spine injured patients, but more likely represents sampling error. These complex patients likely are the "outliers" mentioned by the authors, as treatment of spinal cord injured patients is quite expensive. These patients may increase the overall health expenditure of the 2005 cohort.

3. Population incidence of spine disorders did not significantly change (1997: 15.8%, 2005: 16.7%). This should not imply a failure of treatment, but instead an absence of prevention. The data presented is not longitudinal, and cannot be used to comment on the response of the patient cohorts to therapy[30].

Aetna's policy also offers as further evidence of the lace of utility of lumbar spine fusion procedures the summary prepared by Deyo et al. for the New England Journal of Medicine's "Sounding Board" section. In Deyo's opinion piece, the authors review similar articles to the AANS/CNS guidelines, and conclude that the evidence supporting lumbar fusion is limited. It should be noted that this is an opinion piece, and offers no new insights and no new data to the discussion[31]. Recent reports by Crawford et al. and Glassman et al. attest to the significant potential clinical benefit and improved quality of life in older patients undergoing instrumented lumbar arthrodesis procedures[32, 33].

The Fritzell review is the largest controlled study of lumbar stabilization in the treatment of degenerative disc disease in the lumbar spine. The assessment was completed at 19 centers and employed standard outcomes measures. Patient follow-up was excellent, with 98 percent of patients available for the entire two-year period of the study. This study reported improved clinical outcomes in patients treated surgically, with control group patients undergoing conservative therapy composed primarily of physical therapy. Similarly, surgical patients were more likely to return to work and more likely to note their treatment had been successful[5]. The lack of standardization of conservative treatments mirrors other more recent attempts at randomizing between conservative and operative options in treatment of lumbar pathology[12, 13].

A smaller study completed by Brox et al. used a similar prospective, randomized approach, with standardization of conservative intervention and compared to operatively treated patients with chronic low back pain. The study found no differences between the two arms[34]. The small size of the study may make it under-powered; the shorter follow-up of one year also weakens the validity of this study's approach[35].

Other studies support indications for surgical therapy in lumbar DDD. A recent paper reported the 6-year follow-up of an FDA Phase IV study, combining patients from sites of two previous FDA trials on anterior lumbar interbody fusion for patients with DDD unresponsive to conservative care. This study reported a substantial improvement in patient daily functioning, with improvements in back pain, leg pain, Oswestry disability index (ODI), and Short-form 36 (SF-36) measures[7]. A prospective randomized comparative trial of lumbar arthroplasty versus lumbar fusion assigned 72 adult DDD patients to PLF or PLIF at 1-2 levels. Back pain and ODI scores decreased significantly at 2-years. At 2-years, 76% of fusion patients were back to work part or full time and 67% were satisfied with their surgery[6]. A metaanalysis performed by Bono and Lee reviewed all publications on non-revision fusion for lumbar DDD from during a 20 year period, encompassing over 2000 patients. They report good or excellent clinical outcomes were achieved in over 70% of those treated[36].

There are significant complications which may occur in patients undergoing lumbar spine fusions, as noted by the cited articles compiled from National Inpatient Sample assessments completed by Deyo et al. and by reviews completed by other authors[37]. Disc degeneration may occur in segments

adjacent to fusions in the lumbar and cervical spine. It is unclear whether or not these areas of "juxtafusional" disease are caused by the neighboring fusion or if they represent the natural progression of the lumbar and cervical degenerative processes.

The policy devotes considerable time to reviewing operative outcomes in treatment of failed back surgery syndrome (FBSS). This diagnosis is overly broad, and encompasses a variety of different pathological entities. As noted in the policy, there are a variety of different potential causes for FBSS. Neuroaugmentative therapies may be beneficial for these patients[38]. As noted in the policy, simple discectomy is often sufficient for patients suffering recurrent lumbar disc herniations. However, bony resection during re-exploration of a lumbar disc space may produce iatrogenic instability and require stabilization. The literature, as aptly reviewed in the policy, is poor, comprised primary of non-controlled retrospective reviews.

Treatment precepts gleaned from review of adolescent idiopathic scoliosis may not apply to treatment of the adult, degenerative spine. Hybrid constructs, employing disc arthroplasty devices and lumbar arthrodesis at adjacent motion segments, remain experimental.

The rationale for approval of lumbar disc arthroplasty procedures are well reviewed by the Aetna coverage policy for cervical and lumbar arthroplasty. Approval of lumbar arthroplasty by the US Food and Drug Administration was predicated upon establishing parity in clinical outcomes with the standard of care, lumbar fusion. The acceptance of arthroplasty and refutation of lumbar fusion seems counterintuitive. In the CHARITÉ™ study, there were limited differences between the two groups. Nonetheless, the FDA felt this criteria was adequate for approving the device for widespread use[39].

By the stated Aetna policies for lumbar arthrodesis and lumbar arthroplasty, a patient failing conservative therapy with lumbar degenerative disc disease could be approved for an arthroplasty procedure but denied for an arthrodesis procedure. Considering FDA approval for lumbar arthroplasty was based upon non-inferiority in comparison to lumbar arthrodesis, these policies are not internally consistent.

Concluding Thoughts

Severe and recalcitrant low back pain is a complex and multifactorial problem. It is a life-altering experience for those affected, in subjective impact on par or worse than that of other systemic diseases. Investigations have, to date, not found reliable nonoperative management strategies for patients suffering from severe low back pain.

To date, the highest quality prospective and controlled randomized study of surgery for lumbar DDD showed clear benefits in operatively treated patients[5]. The American Association of Neurological Surgeons and the Congress of Neurological Surgeons, through their collaboration in the NeuroPoint Alliance (NPA), are beginning a prospective accrual of outcomes data in a variety of spine surgery patients. One cohort of patients to be studied will be patients with lumbar degenerative disease undergoing operative therapy. In Washington State, Spine SCOAP is starting as an implementation of the Swedish Spine Registry as a multilateral collaborative between spine surgeons, hospitals, third party insurers and patients. AOSpine North America has initiated an unprecedented patient safety initiative through a series of multicenter studies aimed at improving real time data recording of leading academic spine centers throughout North America. These efforts will provide unprecedented access to real time data regarding utilization, patient safety and outcomes. We hope that, with greater volumes of data available via a patient registry, greater consensus in recommendations for therapy may be achieved.

Again, thank you for this opportunity to comment and assist Aetna in developing an appropriate coverage policy. We are all in agreement about providing quality spine care for our patients, and believe that our suggestions will improve Aetna's current medical policy pertaining to laminectomy and fusion, and ensure that our patients have access to the full range of appropriate and beneficial treatment options. We look forward to seeing a revision to your policy, and would be happy to discuss this further with you in person or on a telephone conference call.

In the meantime, if you have any questions, please feel free to contact John Ratliff, MD (John.Ratliff@jefferson.edu) or Joseph Cheng, MD (joseph.cheng@vanderbilt.edu), AANS/CNS Coding and Reimbursement Committee or Cathy Hill, Senior Manager, Regulatory Affairs AANS/CNS at chill@neurosurgery.org.

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