

# White Paper: Reducing Utilization Concerns Regarding Spinal Fusion and Artificial Disc Implants

For Health Plans, Medical Management Organizations and TPAs

## Executive Summary

Back pain is one of the most common complaints at medical visits. The prevalence and impact of back pain have led to the development of various tests and treatments, including medications, surgical procedures, and implantable devices. Certain patients may benefit from these advances, but the use of new technologies may be expanding to include indications that have not been extensively studied.

Many options are available for the evaluation and management of low back pain, including spinal fusion surgery and artificial disc replacement. However, there has been little consensus on appropriate clinical evaluation and management. Treatment and reimbursement decisions are often based on the Milliman Care Guidelines, which require patients to meet certain requirements before surgery can be considered.

## Introduction

Low back pain (LBP) affects about 90% of Americans at some point in their lives. It is the fifth most common reason for all physician visits in the United States. Total incremental direct healthcare costs attributable to LBP in the United States were estimated at \$26.3 billion in 1998. In addition, indirect costs related to days lost from work are substantial, with approximately 2% of the U.S. workforce compensated for back injuries each year.

The annual number of spinal fusion operations in the United States increased more than 75% between 1996 and 2001. In 2004, spinal fusion surgery accounted for more than \$16 billion in hospital charges (excluding physicians' fees), for more than 300,000 operations. Laminectomies and excisions of intervertebral discs, which decompress nerve roots, added another \$5 billion in hospital fees and another 242,000 inpatient procedures.

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## Treating Low Back Pain

The American College of Physicians and the American Pain Society make the following recommendations for the evaluation of LBP:

- ▶ Clinicians should conduct a focused history and physical examination to help place patients with LBP into one of three broad categories: non-specific LBP, back pain associated with radiculopathy or spinal stenosis, or back pain associated with another specific spinal cause. The history should include an assessment of psychosocial risk factors, which predict the risk for chronic disabling back pain.
- ▶ Clinicians should not routinely obtain imaging or other diagnostic tests in patients with non-specific LBP.
- ▶ Clinicians should perform diagnostic imaging and testing for patients with LBP when severe or progressive neurologic deficits are present or when serious underlying conditions are suspected on the basis of a history and physical examination.

- ▶ Clinicians should evaluate patients with persistent LBP and signs or symptoms of radiculopathy or spinal stenosis with magnetic resonance imaging (MRI) (preferred) or computed tomography (CT), only if they are potential candidates for surgery or epidural steroid injections (for suspected radiculopathy).

The initial evaluation of patients with LBP involves ruling out potentially serious conditions such as an infection, a malignancy, a spinal fracture, or a rapidly progressing neurologic deficit that is suggestive of cauda equine syndrome, bowel or bladder dysfunction, or weakness. These conditions suggest the need for early diagnostic imaging. However, patients without these conditions are initially managed with conservative therapy.

## Conservative Approaches

Conservative management for LBP includes:

- ▶ Avoidance of activities that aggravate pain
- ▶ Chiropractic manipulation in the first four weeks if there is no radiculopathy
- ▶ Cognitive support and reassurance that recovery is expected
- ▶ Education regarding spine biomechanics
- ▶ Exercise program
- ▶ Heat/cold modalities for home use
- ▶ Limited bed rest with gradual return to normal activities
- ▶ Low-impact exercise as tolerated, for example, stationary bike, swimming, or walking
- ▶ Pharmacotherapy, for example, non-narcotic analgesics, nonsteroidal anti-inflammatory drugs (NSAIDs) (as second-line choices). Addictive muscle relaxants should be available or used only during the first week. Narcotics should be avoided.

Generally, conservative therapy is not recommended in the presence of progressive neurological deficits, when a spinal fracture or a dislocation is unstable, or for a progressive spinal deformity.

There is currently no consensus regarding the optimal duration for conservative treatment prior to surgical intervention for low back pain—recommendations range from at least three months to greater than one year.

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## Imaging

Despite guidelines recommending the limited use of imaging, the use of lumbar magnetic MRI has increased by 307% in the Medicare population in a recent 12-year interval. Studies have shown that one-third to two-thirds of spinal CTs and MRI may be inappropriate. Potential factors driving the increased use of imaging may include patient demand, the desire for visual evidence, the fear of lawsuits, and financial incentives.

Based on an extensive systematic review, the American College of Physicians and the American Pain Society explicitly recommend against routine imaging in patients with non-specific LBP (in other words, patients without severe or progressive neurologic deficits or evidence of serious underlying conditions).

## Surgery

When conservative management is attempted and fails, surgery may be indicated for persistent back pain that involves an anatomical problem, (for example, a herniated disc, spinal stenosis, or spondylolisthesis).

Surgical procedures for LBP include:

- ▶ Discectomy: the surgical removal of herniated disc material that presses on a nerve root or the spinal cord.
- ▶ Laminectomy (spinal decompression): An open surgical procedure that involves removing a small portion of bone in the spine, called the lamina, in order to alleviate pressure on the spinal nerves. Fragments of a ruptured disc may also be removed during surgery.
- ▶ Spinal fusion: a procedure that joins two bones (vertebrae) in the spinal column together to eliminate pain caused by movement.
- ▶ Artificial disc replacement: a relatively new procedure that is an alternative to spinal fusion when the cause of injury is a degenerated disc. An artificial disc is used to replace the damaged disc.

## Spinal Fusion

Strictly defined, spinal fusion is an operation that's designed to treat spinal instability. Specific patient selection guidelines for lumbar fusion have not been well defined in the medical literature. This is likely due to several issues: the current definitions of spinal instability are not uniformly accepted and applied; it is difficult to measure instability in individual clinical circumstances; and scientific evidence regarding spinal fusion is limited. Therefore, clinical practice is guided by an understanding of the principles of spinal biomechanics and by the knowledge of the generally accepted indications, contraindications, and controversies regarding fusion surgery. Factors to be considered include the patient's history, the physical exam, response to conservative measures, the psychosocial profile, the diagnostic test results, and the physician's expertise.

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Although many conditions of the spine benefit from spinal fusion, spinal fusion for chronic LBP remains controversial. Studies have shown that the benefits of spinal fusion surgery are limited when treating degenerative discs with back pain alone (no sciatica). In the past, many surgeons would not perform spinal fusions for back pain alone because of inconsistent outcomes and the significant potential risks and complications that are associated with spinal fusion.

Some have suggested that the significant increase in the number of spinal fusions has been driven by financial incentives that exist for device manufacturers and for neurosurgeons. Other factors contributing to the recent rapid rise in the number of spinal fusions include an aging population, improved axial imaging technology, technological improvements in spinal fixation devices, and refinements in spinal surgical procedures.

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## Milliman Care Guidelines for Lumbar Fusion

Insurance companies often base coverage decisions on the Milliman Care Guidelines for lumbar fusion (please see Table 1), which consider the procedure medically necessary in a few instances, including when the patient has a spinal fracture and spinal instability or neural compression; spinal repair in operations for a dislocation, an abscess, or a tumor; and spinal tuberculosis. For degenerative scoliosis, the guidelines indicate that the patient must have a deformity of greater than 50 degrees with loss of function, persistent significant radicular pain or weakness, or persistent neurogenic claudication that is unresponsive to conservative care. Further recommendations for spinal fusions to treat stenosis and spondylolysis have specific requirements that patients must achieve before surgery is recommended.

**Table 1. Milliman Care Guidelines for Lumbar Fusion**

- ▶ Procedure may be indicated for one or more of the following
  - Spinal fracture with one or more of the following:
    - ◆ Spinal instability
    - ◆ Neural compression
  - Moderate to severe lumbar spinal stenosis associated with lumbar spondylolisthesis or with evidence of spinal instability, either pre-existing or anticipated due to the need for bilateral decompression or wide decompression involving facetectomy or resection of pars interarticularis
  - Spondylolisthesis with one or more of the following:
    - ◆ Progressive deformity or neurologic compromise
    - ◆ Pediatric (age ≤18) patients with high-grade (i.e., 50% or more anterior slippage) spondylolisthesis demonstrated on x-ray
    - ◆ Adult patients (age >18) with persistent and significantly symptomatic, despite an adequate trial of at least six months of conservative care, low- or high-grade spondylolisthesis demonstrated on x-ray
  - Spinal repair (if needed) in operations for one or more of the following:
    - ◆ Dislocation
    - ◆ Abscess
    - ◆ Tumor
  - Severe degenerative scoliosis with one or more of the following:
    - ◆ Progression of deformity to greater than 50 degrees with loss of function
    - ◆ Persistent significant radicular pain or weakness unresponsive to conservative care
    - ◆ Persistent neurogenic claudication unresponsive to conservative care
  - Spinal tuberculosis
  - As a surgical adjunct to disc excision or reoperative discectomy in patients with radiculopathy secondary to a herniated disc in whom there is documented radiographic evidence of preoperative lumbar spinal instability (e.g., anterolisthesis, retrolisthesis, spondylolisthesis)

According to the Milliman Care Guidelines, lumbar fusion is considered to not be medically necessary when one of the indications listed in Table 1 is not present, including but not limited to:

- ▶ As a procedure following primary disc excision, including patients with a herniated lumbar disc causing radiculopathy
- ▶ As a treatment for LBP due to degenerative disc disease or degenerative lumbar spondylosis without stenosis or spondylolisthesis

## Artificial Disc Replacement

Artificial disc prostheses were developed as a means to improve flexibility, to maintain spinal curvature, and to provide an equalized weight-bearing surface while reducing or possibly eliminating back pain. However, artificial disc replacement remains controversial. It is approved by the FDA for single-level disc replacement (lumbar), and may be appropriate for only a very limited group of patients. In addition, the FDA has required post-procedure review of safety and efficacy for five to seven years as a requirement for FDA approval of these device; these studies have not yet been completed. Without the long-term studies on safety and efficacy, the present use of these devices remains experimental in nature. Potential complications include death, major bleeding, or severe nerve injury. Patients with multiple degenerating discs or who have had multiple failed back surgeries may not be candidates for artificial disc replacement.

There is also a device to replace only the nucleus pulposus, the soft inner part of the disc. The role of these new technologies has not yet been established, and there are limited data on long-term outcomes.

## Role of External Independent Medical Review

An independent medical review, which is normally used by healthcare payers, looks at whether or not a specific procedure was medically necessary. The physician specialists who work with independent review organizations keep up-to-date with the latest medical research literature and with the latest standard of care. This is especially important since spinal fusion continues to undergo controversy as its technology evolves and as treatments frequently go from being experimental/investigational to the standard of care. Independent medical reviews also avoid conflicts of interest, which can relate to economics, lack of specialists to review cases, or having the same doctor who denied a case review an appeal.

## Conclusions

The rapidly increasing use of spinal surgeries has generated concerns about the safety, effectiveness, and cost of these procedures. As healthcare organizations attempt to stay up-to-date on the latest approved, and experimental, techniques, spine surgeons face the ongoing challenge of making sure that patients are receiving the highest quality of care. The Milliman Care Guidelines for lumbar fusion clearly define spinal instability issues, and indicated that patients must meet certain requirements before surgery can be considered. At this point, artificial disc replacement surgery is still considered experimental, and many healthcare plans are scrambling to approve these surgeries in the absence of long-term data.

Spinal fusion remains very popular despite the significant risks and questionable outcomes. Continual technological developments often complicate the process of establishing evidence-based criteria for practice guidelines and reimbursement policies. Clinicians may be driven by financial incentives to perform more lucrative procedures. Many insurance companies now recommend a second opinion before spinal fusion.

External independent medical review facilitates safe and effective treatment of LBP, which requires an in-depth understanding of the evaluation and treatment of LBP, so that treatments can be individualized for each patient.

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