

Surgical Guideline for Lumbar Fusion (Arthrodesis)

I. Introduction

The purpose of this guideline is:

- A. To provide utilization review staff with the information necessary to make recommendations about the medical necessity and clinical appropriateness of lumbar fusions.
- B. To serve as an instructional aid for physicians when treating injured workers who present with low back pain and associated symptoms that have developed in the context of routine work activity, and whose condition does NOT include:
 - spinal fracture or dislocation
 - spinal infection
 - spinal deformity (e.g. one related to degenerative scoliosis)

NOTE: Special requirements apply when requesting lumbar fusion for patients with uncomplicated degenerative disc disease. Refer to Section VIII of this guideline and WAC 296-20-12065 for definitions, criteria, and requirements.

II. Conservative care

Conservative care consisting of both A and B below should be tried first. If the patient has a progressive neurological deficit, these can be waived:

- A. The surgeon requesting the lumbar fusion should have personally evaluated the patient on at least two occasions prior to requesting the fusion and
- B. The patient should have at least three months of conservative therapy for low back pain, which predominantly emphasizes physical reconditioning.

III. Surgical criteria for patients with no prior lumbar surgery

If conservative care has failed to relieve symptoms and the patient has had no prior lumbar surgery, a lumbar fusion should be considered only if one or more of the following criteria have been met:

- A. The patient demonstrates mechanical (non-radicular) low back pain with instability.

Instability of the lumbar segment is defined as at least 4mm of anterior/posterior translation at L3-4 and L4-5, or 5mm of translation at L5-S1 or 11 degrees greater end plate angular change at a single level, compared to an adjacent level. Adequate flexion/extension views should be taken utilizing

techniques that minimize the potential contribution of hip motion to perceived lumbar flexion or extension.

Note: Only single level fusions will be approved for patients with no prior lumbar surgery.

- B. The patient has at least Grade 2 spondylolisthesis with one or more of the following:
1. Objective signs/symptoms of neurogenic claudication OR
 2. Objective signs/symptoms of unilateral or bilateral radiculopathy, which are corroborated by neurologic examination and by MRI or CT (with or without myelography) OR
 3. Instability of the lumbar segment as defined above in section III-A.

IV. Surgical criteria for patients with prior lumbar surgery

Surgical criteria for patients with prior lumbar surgery vary depending on the *location and type of previous surgery*:

- A. If conservative care has failed to relieve symptoms and the patient has had a *prior laminectomy, discectomy, or other decompressive procedure* at the same level, lumbar fusion should be considered only if the patient has one or more of the following:
1. Mechanical (non-radicular) low back pain with instability (as defined above in Section III-A) at the same or adjacent levels OR
 2. Mechanical (non-radicular) low back pain with pseudospondylolisthesis, rotational deformity or other condition leading to a progressive (measurable) deformity OR
 3. Objective signs/symptoms compatible with neurogenic claudication or lumbar radiculopathy that is supported by MRI or CT (with or without myelography) and by a detailed clinical neurological examination OR
 4. Evidence from a post-laminectomy structural study of either:
 - a. 100% loss of facet surface area unilaterally, OR
 - b. 50% combined loss of facet surface area bilaterally
- B. If conservative care has failed to relieve symptoms and the patient has had a *prior fusion at the same level*, lumbar fusion should be considered only if the patient has one or more of the following:
1. Pseudarthrosis with or without hardware failure, confirmed by objective evidence of pseudarthrosis (e.g. abnormal thin slice CT scan)
 2. Neurogenic claudication supported by either MRI, CT, or myelography
 3. Lumbar radiculopathy supported by either MRI, CT, or myelography, or supported by a detailed clinical neurological or neurosurgical examination.

- C. If conservative care has failed to relieve symptoms and the patient has had a *prior fusion at a level adjacent to the new one being considered*, lumbar fusion should be considered only if the patient meets the same criteria as described for patients with no prior lumbar surgery (see section III above).

V. Contraindications for lumbar fusion

There are important contraindications for lumbar fusions, even when patients meet the criteria described in the previous sections:

- A. Absolute contraindications
1. Lumbar fusion is not indicated with an initial laminectomy/diskectomy related to unilateral compression of a lumbar nerve root.
- B. Relative contraindications
1. Severe physical de-conditioning
 2. Current smoking ^{1,2}
 3. Multiple level degenerative disease of the lumbar spine
 4. Greater than 12 months of disability (e.g. time-loss compensation benefits) prior to consideration of fusion
 5. No evidence of functional recovery (e.g. return to work) for at least six months following the most recent spine surgery
 6. Psychosocial factors that are correlated with poor outcome, such as:
 - a. History of drug or alcohol abuse
 - b. High degrees of somatization on clinical or psychological evaluation
 - c. Presence of a personality disorder or major psychiatric illness
 - d. Current evidence of factitious disorder

VI. Research-based findings related to lumbar fusion outcomes among injured workers in Washington State

- A. Studies among injured workers in Washington State showed the following postoperative outcomes ^{3,4}:
1. The chance of an injured worker no longer being disabled 2 years after lumbar fusion is 32%.
 2. More than 50% of workers who received lumbar fusion through the Washington workers' compensation program felt that both pain and functional recovery were no better or were worse after lumbar fusion.
 3. The overall rate of re-operation within 2 years for all fusions is approximately 23%.
 4. Smoking at the time of fusion greatly increases the risk of pseudarthrosis ^{1,2}.
 5. Pain relief, even when present, is not likely to be complete (Please see VI.B. below).
 6. The use of spine stabilization hardware (metal devices) in Washington workers nearly doubled the chances of having another surgery.

- B. There are mortality risks following lumbar fusion in Washington State's Workers' Compensation patients (State Fund only) ⁵. It should be noted that these effects are not likely related directly to the lumbar fusion procedure per se, but to inadequacy of pain relief or to worsening of pain following fusion:
1. Three years after lumbar fusion, nearly 2% of the workers had died.
 2. The cause of death, accounting for 21% of all deaths and 31% of all potential life lost, was most often associated with prescription drugs given for pain relief. Opioid analgesics were associated with 91% of these deaths.
 3. All analgesic-related deaths occurred among workers who had either intervertebral cage devices or instrumentation.
 4. Degenerative disc disease is associated with an increased risk of analgesic-related death (rate ratio, 2.71) especially among workers aged between 45-54 years (rate ratio, 7.45).
 5. Repeat fusions carry a higher risk of post-operative mortality at 90 days.

VII. When the physician wants to proceed with a lumbar fusion request

- A. The operating surgeon should follow the lumbar fusion patient at least every two months for the first six postoperative months. At the six month examination, if the patient is still experiencing significant pain, a face to face evaluation should be conducted, which includes all of the following elements:
1. Neurologic examination
 2. Imaging study to rule out pseudarthrosis (e.g. thin slice CT)
 3. Repeat flexion-extension films to rule out instability (as defined in III-A)

If no new objective neurologic signs are found, and if there is no objective evidence of fusion failure, the patient may have reached maximum medical improvement and an impairment rating (permanent partial disability (PPD) assessment) may be appropriate.

- B. Prior to lumbar fusion, clinical psychological or psychiatric assessment should be performed on all patients who meet the lumbar fusion criteria and who have been receiving time-loss compensation benefits. This assessment is intended to help the requesting surgeon identify specific psychological risk factors for chronic disability that may be barriers to recovery following lumbar fusion.
- C. All intraoperative determinations of instability that lead to fusion must be clearly documented at the time, and (if requested by L&I) subsequently discussed with a peer surgeon.
- D. Diagnostic facet joint injections and pain relief during the use of a rigid spinal brace are not definitive indications for fusion.
- E. Pre-surgical discography is not covered.

- F. Anterior Lumbar Interbody Fusion (ALIF), if indicated, should be done only in conjunction with a posterior stabilization procedure.
- G. Prior to surgery, the physician and patient should review and sign the information form included with this guideline. This should be kept in the chart.

VIII. Special requirements for patients with degenerative disc disease

Special requirements exist for patients for whom a single level lumbar fusion is requested related to uncomplicated degenerative disc disease (UDDD). Uncomplicated degenerative disc disease as defined in WAC 296-20-12065 means chronic low back pain of discogenic origin without any evidence of the following conditions:

- Radiculopathy,
- Functional neurologic deficits,
- Spondylolisthesis (greater than grade 1),*
- Isthmic spondylolysis,
- Primary neurogenic claudication associated with stenosis,
- Fracture, tumor, infection, inflammatory disease,
- Degenerative disease associated with significant deformity

* Workers who do not meet the instability criteria outlined in section III and who have less than Grade 2 spondylolisthesis will be considered to have Uncomplicated DDD.

For these patients, if three months of conservative therapy fail to relieve pain or restore function to an acceptable level, the patient's attending provider should refer him or her to a SIMP for a chronic pain management evaluation and treatment of any accompanying complicating clinical issues (eg, opioid dependence, depression). If a lumbar fusion is requested, the patient must complete SIMP treatment before the surgery can be considered and potentially authorized.

If the patient cannot participate in and complete SIMP treatment due to other comorbid conditions, the patient's attending provider will arrange for the appropriate treatment.

These special requirements were developed following a coverage decision made in November 2007 by the Washington State Health Technology Clinical Committee (enabled by RCW 70.14.120). Their decision was that lumbar fusion could be a covered treatment option for patients with single level UDDD if treatment by a Structured Intensive Multidisciplinary Program (SIMP) for chronic pain management was completed first and their pain was still unresolved. The coverage decision permits requiring successful completion of a Structured Intensive Multidisciplinary Program (SIMP) as a prerequisite for lumbar fusion for UDDD. The clinical committee's decision was based on research that showed a SIMP for chronic pain management is as effective as fusion surgery, while avoiding the risks and potential complications associated with surgery⁶. This conclusion was based on research that demonstrated:

1. There is no clinically meaningful difference in outcomes (pain relief, disability improvement) between fusion and intensive exercise/rehabilitation plus cognitive behavioral therapy (CBT) in patients with uncomplicated DDD and either no prior surgery^{7,8} or one prior decompressive procedure⁹.
2. Evidence is insufficient to determine whether lumbar fusion provides equivalent or greater likelihood of return to work compared to intensive exercise/rehabilitation plus CBT.
3. Evidence is insufficient to determine what patient characteristics are associated with differences in the benefits and adverse events of lumbar fusion surgery.
4. Lumbar fusion leads to higher rates of both early and late adverse events compared with intensive exercise/rehabilitation plus CBT. Categories of adverse events most frequently reported include: reoperation, infection, various device-related complications, neurologic complications, thrombosis, bleeding/vascular complications, and dural injury.

Information about SIMP services can be found in Provider
Bulletin 09-07:

<http://www.lni.wa.gov/ClaimsIns/Files/Providers/ProvBulletins/PbFiles/PB0907.pdf>

The Washington Administrative Code for SIMP services (WAC 296-20-12055 through 296-20-12095) can be found at:

<http://www.lni.wa.gov/ClaimsIns/Rules/MedicalAid/Rule29620/Chapter29620.asp>

What You Should Know About Lumbar Fusion Surgery (Applies to all workers considering lumbar fusion, regardless of diagnosis)

Labor & Industries (the department) has created this information form so you will know how lumbar fusion surgery may affect your health and recovery. The department requires your doctor to discuss this information with you before the surgery so you can make the best decision possible. After you have read and discussed this information, both you and your doctor should sign your names at the end of this form. **This is NOT a surgical consent form.**

Studies³⁻⁵ conducted by researchers at the University of Washington showed that in Washington State workers:

1. About two out of three workers who receive a lumbar fusion are still disabled two years later.
2. More than half of the workers who received lumbar fusion felt that neither their pain nor their ability to function were better after the surgery.
3. Almost one out of four workers who had fusion surgery received another operation within two years
4. If a fusion was redone, the chances of being disabled 2 years later increased by 25%.
5. Smoking at the time of fusion greatly increases the risk of failed fusion^{1,2}.
6. The use of spine stabilization hardware (metal devices) in Washington State workers nearly doubled the chances of needing another surgery.
7. Pain relief, even when present, is not likely to be complete
8. Some lumbar fusion patients have died while taking pain medicine following surgery. Most of these deaths were linked with taking opioids (narcotics). The chances of dying were even higher for those whose fusion was for degenerative disc disease or who had a fusion at more than one vertebral level.

It should also be noted that the studies relied upon for the WA Health Technology Assessment program lumbar fusion decision⁶⁻⁹ and that formed the basis of this amendment to the prior lumbar fusion guideline were not conducted among injured workers or in a workers' compensation population. The outcomes cited above represent the overall outcomes among WA injured workers who have received lumbar fusion.

What is expected of you if you proceed to have a lumbar fusion:

If the Department authorizes your surgery, I will continue to see you at least every two months for six months after the surgery. Both prior to and following surgery, I expect you to actively participate in reactivation and in maintaining any gains you made in the Structured Intensive Multidisciplinary Program (SIMP). After you have had the fusion and have completed the recommended post-operative rehabilitation treatment, if there are no new objective neurologic signs (problems) or evidence that the fusion is not solid, you may have reached maximum medical improvement. Even if you still have pain, I will consider your case to be stable and will ask for an impairment rating to complete your care. If you continue to have pain after your surgery and I cannot find a medical reason for it, the department may not continue to pay for further medical care.

By signing this form, we (the *patient* and *physician*), attest that we have discussed the information presented here, we understand this information, and we wish to proceed with the fusion surgery. **We also understand that this information does NOT take the place of, and is separate and distinct from, any surgical consent form that we will complete prior to surgery.**

Patient Name

Date: ____/____/____

Physician Name

Date: ____/____/____

References:

1. Brown WC, Orme TJ, Richardson H. The rate of pseudarthrosis (surgical nonunion) in patients who are smokers and patients who are nonsmokers: a comparison study. *Spine* 1986;11:942-943.
2. Jenkins LT, Jones AL, Harms JJ. Prognostic factors in lumbar spinal fusion. *Contemp Orthop* 1994;29(3):173-180.
3. Franklin GM, Haug J, Heyer NJ, McKeefrey SP, Picciano JF. Outcome of lumbar fusion in Washington State workers' compensation. *Spine* 1994;19(17):1897-1904.
4. Juratli SM, Franklin GM, Mirza SK, Wickizer TM, Fulton-Kehoe D. Lumbar fusion outcomes in Washington State workers' compensation. *Spine* 2006;31(23):2715-2723.
5. Juratli SM, Mirza SK, Fulton-Kehoe D, Wickizer TM, Franklin GM. Mortality after lumbar fusion surgery. *Spine* 2009;34(7):740-747.
6. <https://www.hca.wa.gov/search/lumbar>, Accessed 10/14/2009
7. Brox JI, Sorensen R, Friis A, Nygaard O, Indahl A, Keller A, Ingebrigtsen T, Eriksen HR, Holm I, Koller AK, Riise R, Reikeras O. Randomized controlled trial of lumbar instrumented fusion and cognitive intervention and exercises in patients with chronic low back pain and disc degeneration. *Spine* 2003;28(17):1913-1921.
8. Fairbank J, Frost H, Wilson-MacDonald J, Yu L, Barker K, Collins R. Randomised controlled trial to compare surgical stabilisation of the lumbar spine with an intensive rehabilitation programme for patients with chronic low back pain: the MRC spine stabilisation trial. *BMJ* 2005;330(7502):1233.
9. Brox JI, Reikeras O, Nygaard O, Sorensen R, Indahl A, Holm I, Keller A, Ingebrigtsen T, Grundnes O, Lange JE, Friis A. Lumbar instrumented fusion compared with cognitive intervention and exercises in patients with chronic back pain after previous surgery for disc herniation: a prospective randomized controlled study. *Pain* 2006;122:145-155.