



**Kaiser Foundation Health Plan
of Washington**

**Clinical Review Criteria
Spinal Fusion**

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Criteria

***All radiology studies (X-ray, MRI, etc.) must be submitted in a written form: films must be read by a Radiologist.**

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	See also the following Medicare Technology Center article - Spinal Fusion for the Treatment of Low Back Pain Secondary to Lumbar Degenerative Disc Disease
KPWA Medical Policy	Due to the absence of a NCD, LCD, or other coverage guidance, KPWA has chosen to use their own Clinical Review Criteria, "Spinal Fusion," for medical necessity determinations. Use the Non-Medicare criteria below.

For Non-Medicare Members

LUMBAR SPINE

Spinal Fusion may be indicated for **ONE or more** of the following

- 1) Spinal fracture (acute) repair indicated by **ONE or more** of the following:
 - Spinal instability due to trauma
 - Neural compression due to trauma
- 2) Lumbar spinal stenosis treatment indicated by **ALL of the following**:
 - Imaging findings of lumbar spondylolisthesis
 - Spondylolisthesis for spine fusion (> or equal to 4 mm).
 - Clinically important findings of spinal stenosis indicated by **ONE or more** of the following:
 - i. Progressive or severe symptoms of neurogenic claudication or radicular pain requiring treatment as indicated by **ALL of the following**:
 - Significant functional impairment
 - Central, lateral recess or foraminal stenosis demonstrated on imaging (e.g., MRI, CT myelography)
 - Failure of at least 3 months of non-operative therapy
 - ii. Severe or rapidly progressive symptoms of motor loss, neurogenic claudication or cauda equina syndrome
- 3) Spondylolysis treatment indicated by **ONE or more of the following**:
 - Rapidly progressive spondylolisthesis with severe neurologic compromise (eg, urinary incontinence)
 - Spondylolisthesis with significant associated findings, including **ALL of the following**:
 - i. Grade 2 or more with (anterior slippage, **not retro slippage as an indicator**) spondylolisthesis demonstrated on plain x-rays, CT or MRI

- ii. Back pain, neurogenic claudication symptoms, or radicular pain from lateral recess or foraminal stenosis
 - iii. Significant functional impairment
 - iv. Failure of at least 3 months of non-operative therapy
- 4) Severe degenerative scoliosis treatment with progression of deformity to greater than 30 degrees or 6mm of slippage (olisthesis) having failed 3 months medical therapy and with **ONE of the following**:
- i. Persistent significant radicular pain or weakness unresponsive to non-operative therapy
 - ii. Persistent neurogenic claudication unresponsive to non-operative therapy
- 5) Anticipated spinal instability due to **ONE or more of the following**:
- Planned extensive surgery for dislocation, infection, abscess or tumor
 - Current plan for additional primary or revision spinal surgeries (e.g., laminectomy).
- 6) Spinal instability due to prior surgery for neural decompression including laminectomy, dislocation, infection, abscess or tumor.
- 7) Revision fusion surgery due to **ONE of the following**:
- For adjacent segment disease as indicated by **ALL of the following**:
 - i. Radiographic evidence of adjacent segment disease (e.g., neural compression) that correlates with symptoms
 - ii. Persistent disabling symptoms (low back pain, radiculopathy)
 - iii. Failure of 3 months of non-operative therapy
 - Documented pseudoarthrosis (nonunion of prior fusion) by radiological studies when **ALL of the following** are met:
 - i. Previous fusion at least 6 months ago with significant interval improvement
 - ii. Persistent daily axial back pain with or without neurogenic claudication or radicular pain
 - iii. Significant functional impairment inability to perform activities of daily living, school, and work
 - iv. Failure of 3 months of non-operative therapy
 - Recurrent same level disc herniation when **ALL of the following** are met:
 - i. Previous disc surgery greater than 6 months ago with interval improvement
 - ii. Recurrent neurogenic claudication or radicular pain unresponsive to non-operative treatment for greater than 3 months
 - iii. Neural structure compression documented by recent imaging consistent with signs and symptoms.

The following are not considered medically necessary:

- a) A lumbar fusion for a spinal deformity not meeting one of above criteria performed primarily for low back pain.
- b) A lumbar fusion performed for any condition not listed above, including non-radicular pain with common degenerative changes (degenerative disc disease, facet joint arthrosis, etc.) or post-laminectomy low back pain.

[Allograft](#) and autograft use in spinal fusion is covered if the requested procedure meets the criteria above for a spinal fusion procedure.

[Minimally Invasive Lumbar Decompression](#) - There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

[Minimally Invasive Sacroiliac Joint Fusion \(iFuse Implant System™\)](#)

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

[Axial Lumbar Interbody Fusion System](#)

There is insufficient evidence in the published medical literature to show that this procedure is as safe as standard procedures and/or provides better long-term outcomes than current standard procedure.

<p>The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, KPWA will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.</p>

Background

Chronic lower back pain is a major health problem and cause of disability in Western countries. The cause of the persistent pain is not well understood for the majority of patients. It generally occurs without specific damage or signs that can be revealed by imaging or other neurophysiological techniques. It is believed that the pain starts as acute pain of muscle and connective tissue and persists among approximately one third of the patients (Rittweger 2002). Mechanical low back pain may have various causes including degenerative disc disease, degenerative spondylosis, disc herniation, facet arthropathy, and others. Patients with low back pain may also experience reduced lumbar flexibility, reduced flexion-relaxation and static balance. The pain is aggravated by sitting, standing and lifting, which increase axial loading on the spine. Walking may relieve some of the pain but patients experience more relief by lying down as it unloads the spine and reduces intradiscal pressure (Gose 1998).

Conservative medical care for chronic back pain includes bed rest, steroid injection, anti-inflammatory drugs, muscle relaxants, conventional physiotherapy, exercises, stretching, manipulative techniques, ultrasound treatments, electric stimulation techniques and others. These measures ease the pain for some patients but are ineffective, intolerable, or unsuitable for others. Patients not responding to conservative therapy may be offered conventional or percutaneous surgical procedures such as disc space decompression, epidural blocks, and spinal instrumentation. These interventions play an important role in treating patients with low back pain due to herniated disc and degenerative disc problems. However, surgery may not relieve all the pain, and could permanently disrupt the biomechanical and physiological function of the disc. Moreover, not all patients are candidates for surgery.

In patients with non-radicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms, it is recommended that clinicians discuss risks and benefits of surgery as an option (weak recommendation, moderate-quality evidence). The net benefit of lumbar fusion was moderate compared to standard nonsurgical therapy; however, there was no difference between lumbar fusion and intensive rehabilitation.

Medical Technology Assessment Committee (MTAC)

Allogenic Bone for Spinal Fusions- Allograft Bone

BACKGROUND

Arthrodesis of the spine has been performed for decades for various spinal conditions such as fractures, congenital or developmental deformities, arthritis, degenerative disease, disc lesions, tuberculosis and other infections. With the overall intent to prevent movement in painful bones by permanently joining two or more vertebrae, bone grafting is an integral part of the fusion process. The choice of bone graft is dependent on various factors including patient specific disease, type and location of fusion, the number of levels involved, patient and surgeon preference, as well as, surgeon experience. Non-fusion risks should also be taken into consideration such as patient age, gender, tobacco use and the patient's health status (Deyo 2004).

Historically, autograft bone harvested from the iliac crest of the patient who is undergoing the procedure has been the gold standard. This type of graft requires an additional incision during operation, lengthening surgery and causing morbidity associated with harvesting the tissue. It is further limited by, inconsistent size, quantity, and quality of tissue. One alternative to autograft is allogeneic bone graft, or allograft bone, which is harvested from cadaver bone. Allograft bone is typically acquired through a bone bank and can be procured in greater quantities than autograft (Ehrler and Vaccaro 2000).

Currently, there are three types of allograft, fresh frozen bone allograft, freeze dried bone allograft and demineralized freeze-dried bone allograft. Allograft bone is available in different shapes and sizes to fit into the area of the spine where it is needed. Allograft materials are difficult to standardize because of the heterogeneity of the donor tissue. In addition, allografts can be prepared in a number of different ways with the characteristics of a particular allograft affected by its method of preparation. Regulations for allograft bone procurement, as well as screening and testing procedures are extensive and enforced by both the American Association of Tissue Banks and the U.S. Food and Drug Administration (FDA).

While allogeneic bone avoids the common complication of donor site morbidity that occurs with autogenic bone grafting the obvious disadvantage is potential disease transfer. Contaminants and pathologies that may be transferred include viral and bacterial infections, malignancy, systemic disorders or toxins. The allograft bone used in spinal fusion procedures is provided by tissue banks (bone banks) which are regulated by the FDA. With that said, a retrospective review done by Mroz and colleagues in 2009, examined the safety of allograft bone through data from the FDA, recalls of musculoskeletal allografts data from the Center for Disease Control (CDC), and literature reviews. The review identified 59,476 recalls between 1994 and 2007 citing improper donor evaluation,

contamination and infection as the main reasons for recall (Mroz, Joyce et al. 2009). In addition, there have been several reported cases of HIV transmission (Asselmeier, Caspari et al. 1993).

03/04/2014: MTAC REVIEW

Allograft Bone

Evidence Conclusion: *Efficacy* - A meta-analysis of autograft versus allograft in anterior cervical discectomy and fusion (ACDF) was conducted in 2000 by Floyd and Ohnmeiss and concluded that it was not possible to ascertain whether autograft is clinically superior to allograft. When the data from all four studies were pooled, a significantly higher rate of union and a lower incidence of collapse was found with autograft for both one- and two-level fusions. Patient satisfaction and clinical outcomes were not adequately addressed in all of the studies and although autograft has a higher fusion rate than allograft, the clinical results did not rely solely on radiographic results (Floyd and Ohnmeiss 2000). [Evidence Table Allograft bone1] In a comparison of allograft versus autograft in multilevel ACDF with instrumentation, Samartzis et al reported fusion rates of 94.3% and 100% for allograft and autograft, respectively. In this study, nonunion occurred in patients with allograft but this difference was not statistically significant. Excellent and good clinical outcomes were noted in 88.8% of patients. These results should be interpreted with caution as the study was retrospective in nature and only included 80 non-blinded patients. With that said, the authors mention that meticulous surgical technique and patient selection were more important than graft type for successful outcome (Samartzis, Shen et al. 2003). [Evidence Table Allograft bone2] Samartzis and colleagues completed an additional and similar study in 2005 which demonstrated a fusion rate of 100% and 90.3% for allograft and autograft, respectively, in one-level ACDF. Clinical outcomes in relation to graft-type were also analyzed with no statistical differences detected ($P > 0.05$). The study took place at a single institution and was retrospective in nature including only 66 non-blinded participants. (Samartzis, Shen et al. 2005). [Evidence Table Allograft bone3] In a prospective randomized study, Gibson and colleagues reported similar clinical results in 69 patients who received either fresh-frozen allograft or autograft during instrumented posterolateral lumbar fusion. The groups were very similar before operation in terms of back pain and leg pain scores, but the allograft group showed a slightly higher overall pain score, which was statistically significant. After one year, however, the scores from the questionnaire were significantly different in that the group that had received allograft bone seemed to have done better in terms of back pain than those who had received the autograft bone (Gibson, McLeod et al. 2002). [Evidence Table Allograft bone4]

Safety - Both the Gibson et al., and the 2005 Samartzis et al. studies reported no complications associated with allograft bone use, however, it is unclear how systematic they were in collecting this information (Gibson, McLeod et al. 2002; Samartzis, Shen et al. 2005). None of the other studies reported on the safety or adverse events of allogeneic bone grafts when used in spinal fusions. While it appears that allografts have comparable fusion rates with autografts, proper evaluation of the efficacy and safety is difficult to make as the risk of bias throughout the studies was high, especially concerning small population sizes and retrospective, non-randomized or non-blinded studies. Patient risk factors, including body mass index, smoking, age and sex also contribute to the diversity of the study groups. As mentioned previously, surgical technique may have as much influence on fusion as the choice of graft and the contributions of factors such as nutrition, sex, age, bone metabolic factors, and smoking on the success of autograft versus allograft. These variations of standard procedures make it difficult to define the true effectiveness of grafts. Moreover, the absence of standardized fusion criteria and inconsistent outcome reporting creates heterogeneity of studies making it difficult to compare and contrast autograft and allograft across studies. Beyond the question of efficacy, the potential risk of disease transmission is the large concern which, on the whole, did not seem to be adequately addressed by the literature. The use of allograft bone in spinal fusion surgery warrants further clinical studies.

Conclusions:

- There is low quality evidence to support the effectiveness of allogeneic bone grafts for ACDL.
- There is insufficient evidence to determine the effectiveness of allogeneic bone grafts in lumbar surgery.
- There is insufficient evidence to determine the safety of allogeneic bone grafts in both cervical and lumbar spinal fusions.

Articles: The literature search revealed just over 100 studies many of which were case reports examining the performance of allograft for spinal fusion, but very few have been prospectively designed and well conducted. Selection of articles relied on the comparison of allograft to autograft. Studies that combined allograft bone with other materials and studies that compared allograft bone to other spinal fusion techniques were excluded. The following publications were selected for critical appraisal: Floyd, T and Ohnmeiss, D. A meta-analysis of autograft versus allograft in anterior cervical fusion. *European Spine Journal* 2000;9:398-403. [Evidence Table Allograft bone1] Samartzis D, Shen FH, Matthews DK, Yoon T, et al. Comparison of allograft to autograft in multilevel anterior cervical discectomy and fusion with rigid plate fixation. *The Spine Journal* 2003;3:451-459. [Evidence Table Allograft bone2] Samartzis D, Shen FH, Goldberg EJ, An HS. Is autograft the gold standard in achieving radiographic fusion in one-level anterior cervical discectomy and fusion in one-level anterior cervical discectomy and fusion with rigid anterior plate fixation? *2005;30(15):1756-1761*. [Evidence Table Allograft bone3]

Gibson S, McLeod I, Wardlaw D, Urbaniak S. Allograft versus autograft in instrumented posterolateral lumbar spinal fusion. *Spine* 2002;27(15):1599-1603. [Evidence Table Allograft bone4]

The use of allograft bone for spinal fusion does meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Spinal Fusion

09/2011: MTAC REVIEW

Evidence Conclusion: The 2009 APS guideline recommends that clinicians discuss risks and benefits of surgery as an option for patients with non-radicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms; however, they also note that there was no difference between lumbar fusion and intensive rehabilitation (weak recommendation, moderate-quality evidence). The 2009 NICE guideline also recommends considering a referral for an opinion on spinal fusion for patients who have completed an optimal package of care, including a combined physical and psychological treatment program and still have severe non-specific low back pain for which they would consider surgery.

Articles: The literature search did not reveal any new studies that addressed the safety or effectiveness of lumbar fusion for the treatment of chronic low back pain. NICE 2009 Consider referral for an opinion on spinal fusion for people who: Have completed an optimal package of care, including a combined physical and psychological treatment program AND Still have severe non-specific low back pain for which they would consider surgery. American Pain Society (Chou) 2009 In patients with non-radicular low back pain, common degenerative spinal changes, and persistent and disabling symptoms, it is recommended that clinicians discuss risks and benefits of surgery as an option (weak recommendation, moderate-quality evidence). The net benefit of lumbar fusion was moderate compared to standard nonsurgical therapy; however, there was no difference between lumbar fusion and intensive rehabilitation. The literature search revealed several studies published after the 2009 guidelines that addressed the safety or effectiveness of lumbar (spinal) fusion compared to non-surgical interventions for the treatment of chronic low back pain; however, none of these were selected for review because of severe methodological limitations (small sample size, power was not assessed, high level of crossover, etc.). PubMed was searched from July 2008 (NICE literature search date) or November 2006 (APS/ACP literature search date) through July 2011 with the search terms acupuncture, back pain, spinal manipulation, meditation, massage, mindfulness based stress reduction, multidisciplinary rehabilitation, physical therapy, sacroiliac joint injections, corticosteroid injections, epidural steroid injections, spinal injections, spinal fusion, and surgery with variations. Searches were limited to English-language studies of human subjects. Only randomized controlled trials (RCTs), meta-analyses, and clinical trials were included in the review. Reference lists and the related articles function in PubMed were used to identify additional publications. Studies were excluded if they had severe methodological limitations (e.g. small sample size, power and/or ITT analysis were not performed, etc.) or if pain or functional disability was not a primary or secondary outcome.

Reviewed by the content of care committee and not MTAC.

AxialIF

12/16/2013: MTAC REVIEW

Evidence Conclusion: *Efficacy* The literature search revealed five case series that report on outcomes associated with AxialIF. The largest, published in 2011, was a retrospective analysis of 156 patients from 4 clinical sites in the US. Ultimately, the mean pain and ODI scores improved by approximately 63% and 54% respectively ($P < 0.001$) and the overall radiographic fusion rate at 2 years was 94%. The study did not report any adverse events. The patient population was reported to be homogenous, however, the variable nature and progression of the disease compromises the reliability of this claim. Limitations of this study include the retrospective analysis, industry funding as well as selection bias. Outcome measures were not all objective and relied on patient reporting. Only half of the patients were accounted for in the preoperative and postoperative ODI outcome (Tobler, Gerszten et al. 2011). Several smaller case series were also identified and are summarized in a table 1. Ultimately, all of the studies report similar results and conclusions but are subject to the bias of any retrospective series. Further limitations include a lack of control subjects, potential for selection bias as only one of the studies enrolled consecutive patients and unclear study objectives. All studies, with the exception of the publication by Patil and colleagues, received industry funding from TranS1 (Patil, Lindley et al. 2010; Gerszten, Tobler et al. 2012; Marchi, Oliveira et al. 2012). *Safety* Two publications addressed the safety of AxialIF with conflicting results. The first study was a 5-year surveillance study of 9,152 patients (Gundanna, Miller et al. 2011) and the second, a retrospective review of 68 patient records (Lindley, McCullough et al. 2011). Gundanna and colleagues reported minimal complications (1.3%) in their study while Lindley et al. reported high complication rates (23.5%). The observed adverse events across both the studies included pseudoarthrosis, superficial infection, sacral fracture, pelvic hematoma, failure of wound closure, and rectal perforation. Although both studies

were designed to be systematic in their investigation, neither study had a control group for comparison and the results are dependent on either spontaneous reporting or the accuracy of medical records. In addition, both of the studies are subject to a variety of bias due to patient selection and industry funding.

Conclusion: There is insufficient evidence to determine the efficacy of AxiaLIF compared to standard fusion procedures. There is insufficient evidence to establish whether the AxiaLIF is as safe as standard fusion procedures.

Articles: Currently, there are no randomized control trials that compare the AxiaLIF with other approaches to lumbosacral interbody fusion. The literature related to the safety and efficacy is primarily comprised of case series. The following studies were selected for review: Tobler WD, Gerszten PC, Bradley WD, Raley TJ, Nasca RJ and Block JE. Minimally invasive axial presacral L5-S1 interbody fusion. *Spine* 2011;**36**(20):E1296-E1301.

[See Evidence Table](#). Gerszten PC, Tobler W, et al. Axial presacral lumbar interbody fusion and percutaneous posterior fixation for stabilization of lumbosacral isthmic spondylolisthesis. *Journal of Spinal Disorders & Techniques* 2012;**25**(2):E36-E40. [See Evidence Table](#). Marchi L, Oliveira L, et al. Results and complications after 2-level axial lumbar interbody fusion with a minimum 2-year follow up. *Journal of Neurosurgery: Spine* 2012;**17**(3):197-192. [See Evidence Table](#). Patil S, Lindley E, et al. Clinical and radiological outcomes of axial lumbar interbody fusion. *Orthopedics* 2010;**33**(12). [See Evidence Table](#) Aryan H, Newman C, et al. Percutaneous axial lumbar interbody fusion (AxiaLIF) of the L5-S1 segment: initial clinical and radiographic experience. *Minimally Invasive Neurosurgery* 2008;**51**:225-230. [See Evidence Table](#).

The use of AxiaLIF does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Date Created	Date Reviewed	Date Last Revised
10/04/2011	11/01/2011 ^{MDCRPC} , 09/04/2012 ^{MDCRPC} , 06/04/2013 ^{MDCRPC} , 11/05/2013 ^{MDCRPC} , 04/01/2014 ^{MPC} , 07/01/2014 ^{MPC} , 05/05/2015 ^{MPC} , 03/01/2016 ^{MPC} , 01/03/2017 ^{MPC} , 11/07/2017 ^{MPC} , 10/02/2018 ^{MPC}	12/06/2016

^{MPC} Medical Policy Committee

Revision History	Description
12/06/2016	Added clarification to indication: Spondylolisthesis for spine fusion (> or equal to 4 mm)
7/26/2017	Removed spinal decompression codes 22867-22870

Codes

CPT:

Lumbar Spine: 22533, 22534, 22558, 22585, 22612, 22614, 22630, 22632, 22633, 22634, 22800, 22802, 22804, 22808, 22810, 22812, 22840, 22841, 22842, 22845, 22846, 22848, 22849, 22851, 22853, 22854, 22859, 0195T, 0196T, 0309T

Minimally Invasive Lumbar Decompression: 0275T, S2348

Minimally Invasive Sacroiliac Joint Fusion: 0195T, 27279

Axial Lumbar Interbody Fusion: 22586, 0195T, 0196T, 0309T

Allograft & Autograft: 20930, 20931, 20936, 20937, 20938