# MEDICAL POLICY

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| **Medical Policy Title** | **Minimally Invasive / Minimal Access Techniques for Lumbar Interbody Fusion** |
| **Policy Number** | **7.01.83** |
| **Current Effective Date** | June 26, 2025 |
| **Next Review Date** | June 2026 |

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

## POLICY STATEMENT(S)

I. The following minimally invasive/minimal access techniques for lumbar interbody fusion (LIF) are considered **medically appropriate** treatment alternatives to standard open lumbar fusion when the criteria set forth in Corporate Medical Policy #7.01.90 Lumbar Fusion for Adults are met:

   A. Anterior lumbar interbody fusion (ALIF);

   B. Direct lateral interbody fusion (DLIF);

   C. Extreme lateral interbody fusion (XLIF);

   D. Posterior lumbar interbody fusion (PLIF); or

   E. Transforaminal lumbar interbody fusion (TLIF).

II. The following minimally invasive/minimal access techniques for lumbar interbody are considered **investigational** either as stand-alone procedures or as adjuncts to standard spinal fusion:

   A. Pre-sacral interbody fusion, including axial lumbar interbody fusion (AxiaLIF);

   B. Minimally invasive lumbar spinal fusions using direct visualization via endoscopy (endoscopic fusion) or indirect visualization (e.g., percutaneous fusion);

   C. Anterior interbody fusion or implantation of intervertebral body fusion devices using laparoscopic approach, or laparoscopic anterior lumbar interbody fusion (LALIF);

   D. Interlaminar lumbar instrumented fusion (e.g., ILIF);

   E. Interspinous fixation/posterior non-pedicle supplemental fixation devices for spinal fusion (e.g., Affix, Aspen Spinous Process Fixation System, Coflex-F); or

   F. Least invasive lumbar decompression interbody fusion (e.g., LINDIF).

## RELATED POLICIES

Corporate Medical Policy

7.01.90 Lumbar Fusion for Adults

11.01.03 Experimental or Investigational Services

## POLICY GUIDELINE(S)

I. Urgent/Emergent Indications/Conditions

A. The presence of urgent/emergent indications/conditions warrants definitive surgical treatment. Imaging findings noted in the applicable procedure section(s) are required.

1. The following criteria are NOT required for confirmed urgent/emergent conditions:

a. Provider-directed non-surgical management

b. Proof of smoking cessation

c. Absence of unmanaged significant mental and/or behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, opioid and alcohol use disorders)

d. Timeframe for repeat procedure

B. Urgent/emergent conditions for lumbar fusion and/or osteotomy include ANY of the following:

1. Traumatic spinal fractures or dislocations (with or without neural compression) when instability is present or decompression of the spinal canal is anticipated to result in iatrogenic instability

2. Infection (e.g., discitis, epidural abscess, osteomyelitis) when instability is present or debridement and/or decompression is anticipated to result in iatrogenic instability

3. Primary or metastatic neoplastic disease-causing pathologic fracture, cord compression, when instability is present or resection and/or decompression is anticipated to result in iatrogenic instability

4. A condition otherwise meeting criteria listed in the applicable procedure section(s) with documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated.

## DESCRIPTION

Lumbar fusion has become a widely accepted method for the management of a variety of disorders that require spinal stabilization, such as traumatic, degenerative, infectious, and neoplastic conditions. Interbody fusion of the lumbar spine can be approached from an anterior, posterior, or lateral direction. These procedures are traditionally performed with an open approach (long incision with wide retraction of the musculature). One of the drawbacks of conventional lumbar fusion is the extensive soft tissue dissection that is necessary, to expose the anatomic landmarks for screw insertion, to achieve a proper lateral-to-medial screw trajectory, and to develop an acceptable fusion bed. The tissue injury that occurs during the surgical approach can result in increased post-operative

pain, lengthened recovery time, and impaired spinal function. Blood loss during open lumbar fusion surgery can also be quite significant. These conventional approaches can now be performed through minimally invasive/minimal access procedures. A variety of minimally invasive/minimal access procedures are being investigated, with the intent of limiting iatrogenic damage to muscular, ligamentous, neural, and vascular structures. Among the techniques investigated are laparoscopic anterior lumbar interbody fusion (LALIF), posterior lumbar interbody fusion (PLIF), transforaminal lumbar interbody fusion (TLIF), lateral interbody fusion (e.g., Extreme Lateral Interbody Fusion [XLIF] or Direct Lateral Interbody Fusion [DLIF]), and para-axial interbody fusion (AxiaLIF).

Anterior access provides direct visualization of the disc space through an abdominal incision, potentially allowing a more complete discectomy and better fusion than lateral or posterior approaches. An anterior approach avoids trauma to the paraspinal musculature, epidural scarring, traction on nerve roots, and ductal tears. However, the retraction of the great vessels, peritoneal contents, and superior hypogastric sympathetic plexus with a peritoneal or retroperitoneal approach place these structures at risk of iatrogenic injury. Access to the posterior space for the treatment of nerve compression is also limited. Laparoscopic Anterior Lumbar Interbody Fusion (LALIF) is a minimally invasive technique that has been proposed as an alternative to the open surgical approach to spinal fusion. This method employs a laparoscope to remove the diseased disc and insert an implant into the disc space, which is intended to stabilize and promote fusion. This technique is evolving as a method of minimizing soft-tissue injury and is associated with a learning curve.

Posterior LIF can be performed through either a traditional open procedure with a midline incision or with a minimally invasive approach using bilateral paramedian incisions. In the open procedure, the midline muscle attachments are divided along the central incision, to facilitate wide muscle retraction and laminectomy. Minimally invasive/minimal access PLIF uses tubular retractors (e.g., METRx, Luxor), to allow access and open visualization of the surgical area. These tubular retractors may be used to open smaller, central, bilateral working channels to access the pedicles and foramen. Minimally invasive PLIF typically involves partial laminotomies and facetectomies. The decompression allows treatment of spinal canal pathology (e.g., spinal stenosis, lateral recess and foraminal stenosis, synovial cysts, and hypertrophic ligamentum flavum), as well as stabilization of the spine through interbody fusion.

Transforaminal LIF, performed through an open technique, is also performed through a posterior approach. Access to the spine is through the foramen, which is enlarged by removal of surrounding bone. In minimally invasive TLIF, a single incision about 2 to 3 cm in length is made approximately 3 cm lateral to the midline. A tubular retractor is docked on the facet joint complex, and a facetectomy with partial laminectomy is performed. Less dural retraction is needed, with access through the foramen via unilateral facetectomy, and contralateral scar formation is eliminated. TLIF provides access to the posterior elements, along with the intervertebral disc space.

Axial lumbar interbody fusion (AxiaLIF), also called anterior para-axial, trans-sacral or paracoccygeal interbody fusion, is a minimally invasive technique designed to provide anterior access to the L4-S1 disc spaces for interbody fusion. It is performed percutaneously, under fluoroscopic guidance via the pre-sacral space. Theoretically, this approach avoids the viscera, blood vessels and nerves; preserves

normal tissue at the treatment site; provides access to the disc space without interrupting the annulus; and allows for percutaneous longitudinal access to the anterior spine.

Lateral interbody fusion (e.g., Extreme Lateral Interbody Fusion [XLIF] or Direct Lateral Interbody Fusion [DLIF]) uses specialized retractors in a minimally invasive, lateral approach to the anterior spine through the psoas. In comparison with ALIF, the lateral approach does not risk injury to the peritoneum or great vessels. However, exposure to the spine may be more limited, and dissection of the psoas major places the nerves of the lumbar plexus at risk. Electromyographic monitoring and dissection, predominantly within the anterior psoas major, may be utilized to reduce the risk of nerve root injury. These various factors decrease the ability to perform a complete discectomy and address pathology of the posterior elements. The XLIF surgical technique incorporates two systems developed by NuVasive: the MaXcess System and the NeuroVision JJB System.

Both open and minimally invasive/minimal access interbody fusion surgeries may also include decompression of the spinal canal, use of interbody cages, bone grafts, osteoinductive agents (e.g., recombinant human bone morphogenetic protein), and insertion of pedicle screws and rods to increase stability of the spine.

Interlaminar lumbar instrumented fusion (ILIF) combines direct neural decompression with an allograft interspinous spacer to maintain the segmental distraction, and a spinous process fixation plate, or other fixation options such as cortical pedicle screws to maintain stability for eventual segmental fusion (e.g., Coflex-F).

Interspinous fixation (fusion) devices (IFDs) are being developed to aid in the stabilization of the spine. They are evaluated as alternatives to pedicle, screw, and rod constructs in combination with interbody fusion. IFDs are also being evaluated for stand-alone use in patients with spinal stenosis and/or spondylolisthesis.

## SUPPORTIVE LITERATURE

Minimal Access Open Anterior, Posterior, and Transforaminal LIF

The available evidence (reviews, non-randomized comparative studies) suggests that, after an initial training period, the mid-term health outcomes (including complication and fusion rates, pain and function) following minimally invasive anterior, posterior, transforaminal, and extreme lateral interbody fusion (XLIF) approaches are comparable to standard open approaches for single-level interbody fusion of the lumbar spine. Intra- and peri-operative health outcomes (blood loss and hospital stay) have been shown to be improved (e.g., Kim et al., 2010; Park et al., 2007; Ghahreman et al., 2010; Kasis et al., 2009; Wang et al., 2010; Wu et al., 2010; Shunwu et al., 2010; Rouben et al., 2011).

Direct Lateral Interbody Fusion (DLIF)

The DLIF procedure utilizes specialized, FDA-approved instrumentation from Medtronic. While well-designed, comparative clinical trials are needed to demonstrate whether these procedures provide improved health outcomes with long-term follow-up, the outcomes from studies thus far demonstrate that DLIF has comparable outcomes to XLIF. Berjano et al. (2012) conducted a retrospective cohort

review of 97 consecutive patients from three centers, with minimum six-month follow-up (mean 12 months, 93 patients available for follow-up). The main diagnosis was degenerative disc disease (DDD), with or without stenosis, or spondylolisthesis, grade I. Functional status was evaluated by pre-operative and last follow-up Oswestry Disability Index score. Leg and back pain were evaluated by visual analog scales. Complications were recorded, and permanent complications and neurological impairment were actively investigated at last follow-up. Clinical success was considered to be achieved when the patient increased functional ODI score by more than 12% or decreased back pain VAS by more than three points. No permanent neurological impairment or vascular or visceral injuries were observed by the investigators. Transient neurological symptoms presented in 7% of cases; all resolved within one month from surgery. Transient thigh discomfort was observed in 9% of cases. Clinical success was recorded in 92% of cases.

Extreme Lateral Interbody Fusion (XLIF)

While XLIF as an endoscopic surgical procedure does not require FDA approval, the instrumentation associated with the XLIF procedure does. NuVasive has developed the XLIF instrumentation/products for this surgical approach. This minimally invasive surgical platform is known as Maximum Access Surgery (MAS). MAS combines three categories of product offerings: NeuroVision, MaXcess, and specialized implants such as SpheRx and CoRoent. All surgical instrumentation associated with this procedure has received FDA approval either through the pre-market approval or Section 510(k) process.

Ozgur et al. (2006) reported on the surgical technique for XLIF of the lower lumbar spine. Thirteen patients with axial low back pain who failed at least six months of conservative management underwent the XLIF technique. The authors concluded that, in comparison to anterior laparoscopic approaches, the XLIF approach had the advantages of not needing to retract the great vessels, not requiring a steep learning curve, and no impairment to depth perception during the procedure. The most important advantage was a reduction in operative time. In this preliminary report, no complications were associated with the surgery.

In a 2009 report, Knight and colleagues compared complications from a series of 58 patients who underwent XLIF or DLIF (1- to 3-level) with a historical cohort of patients who underwent open posterolateral lumbar fusion. Thirteen patients (22.4%) experienced a mild or major complication. Nine of the complications were approach-related (two L4 nerve root injuries, six cases of meralgia paresthetica, and one case of significant psoas muscle spasm). In four additional cases, the procedure was aborted because of concerns about nerve proximity. Compared with the historical cohort, there was less blood loss (136 versus 489 mL), a shorter operative time (161 versus 200 mins.), a similar hospital stays (five days), and a similar percentage of complications (22.4 versus 22.5%). Approach-related complications in the open cohort included wound infection and dural tears.

In 2010, Rodgers et al. published a retrospective review of a database for all patients treated with the XLIF procedure by a single surgeon between 2006 and 2008, focusing on early complications (at less than three months) in obese and non-obese patients. Out of a total of 432 patients treated with XLIF during this period, 313 (72%) met the inclusion criteria for the study and had complete data; 156 were obese (greater than 30 kg/m2) and 157 were not obese. Patients who were obese were

slightly younger (58.9 versus 62.9 years of age) and had a higher incidence of diabetes mellitus (48 versus 17) than patients who were not obese but were otherwise comparable at baseline. There were 27 complications (8.6%) in the entire group, which included cardiac and wound complications, vertebral body fractures (one requiring reoperation), nerve injuries, gastrointestinal injuries (one requiring reoperation), and hardware failures (one requiring reoperation for recurrent stenosis after cage subsidence). The complication and reoperation rates were not significantly different between the obese and non-obese groups. There were no cerebrospinal fluid leaks, no infections, and no required transfusions. The average length of hospital stay was 1.2 days. The authors noted that reliable automated neurological monitoring and fluoroscopic guidance, as well as meticulous attention to operative technique, are required, but early outcomes compared well with traditional interventions.

In 2011, Rodgers and colleagues reported a retrospective analysis of intra-operative and peri-operative complications from all consecutive patients (600 procedures, 741 levels) treated by two surgeons since the XLIF procedure was introduced at their institution. Of those procedures, 485 were single-level, 90 were two-level, and 25 involved three or more levels. The hospital stays averaged 1.2 days. There were 37 complications (6%), classified as medical (60%) or surgical (40%). Surgical complications included four transient post-operative neurologic deficits and one subcutaneous hematoma. There were no wound infections, no vascular injuries, and no intra-operative visceral injuries in this series. At a minimum one-year follow-up, VAS pain scores had decreased from an average 8.8 to 3.1.

Laparoscopic Anterior Interbody Lumbar Fusion (ALIF)

Currently, the published, peer-reviewed scientific literature does not allow strong conclusions regarding the overall benefit and long-term efficacy of the laparoscopic anterior approach, compared to open spinal fusion. Studies also report a potentially higher rate of complications with laparoscopic ALIF.

In review of the literature on laparoscopic ALIF, Inamasu et al. (2005) identified 19 studies that described the outcome of a L5-S1 laparoscopic ALIF, nine studies that described the outcome of the L4-L5 laparoscopic ALIF, and eight studies that described the outcome of a two-level laparoscopic ALIF. The review concluded that there was no marked difference between laparoscopic ALIF and the open or mini-open ALIF, in terms of short-term efficacy (operative time, blood loss, and length of hospital stay), but there was a higher incidence of complications. In addition, the conversion rate to open surgery was considered to be high. It was noted that, at the time of the review article, some spine surgeons were abandoning the laparoscopic approach and switching to mini-open ALIF.

The largest trial on laparoscopic ALIF was a prospective, multi-center (19 surgeons from 10 U.S. centers), investigational device exemption (FDA-regulated) trial, published in 1999 by Regan et al. The study compared short-term outcomes from laparoscopic fusion of the spine (240 consecutive patients) and open ALIF (earlier cohort of 591 similar patients). Inclusion criterion was painful degenerative disc disease consisting of disc space narrowing at one or two contiguous levels (L4-L5 and L5-S1). Single-level fusion was performed on 215 patients using laparoscopy and on 305 patients using the open procedure; two-level fusions were performed on 25 patients via laparoscopy, and 286 patients with the open procedure. In 25 (10%) of the laparoscopy patients, conversion to an open

procedure was required due to bleeding (n=6), anatomic considerations (n=5), adhesions or scar tissue limiting access to the spine (n=8), and technical difficulties in placing the threaded cage (n=6). The hospital stay was modestly shorter for the single-level laparoscopy group (3.3 versus 4 days), but not for patients undergoing two-level laparoscopy. Operative time was increased (201 versus 142 minutes) for the single-level laparoscopic approach (243 minutes for the 25 cases converted to open). For two-level laparoscopy, the procedure time was 146 minutes longer than for the open approach. The reoperation rate for single-level procedures was 4.7% in the laparoscopy group, compared with 2.3% in the open group (not significantly different). Major complications (implant migration, great vessel damage, pulmonary embolism) were significantly lower in the laparoscopy group (0% versus 2%). Post-operative complications were similar in the two groups, with an occurrence of 14.1% in the open approach group and 19.1% in the laparoscopic approach group.

A prospective comparison of 50 consecutive patients (25 in each group) with disabling discogenic pain, who underwent single-level or two-level ALIF at L4-L5 with either a laparoscopic or mini-open approach, was reported by Zdeblick and David in 2000. There was no difference between the laparoscopic and mini-open approaches in terms of operating time (125 versus 123 minutes), blood loss (50 cc versus 55 cc), or length of hospital stay (1.4 versus 1.3 days) for single-level fusion. For two-level fusion, the operating time was increased for the laparoscopic procedure (185 versus 160 minutes). There was a 20% rate of complication in the laparoscopic group (disc herniation, ureter injury, iliac vein laceration, transient retrograde ejaculation, deep vein thrombosis) compared with 4% in the mini-open group (ileus). Exposure was considered inadequate in the laparoscopic group, with only a single interbody cage placed in 16% of patients in the laparoscopic group. All patients in the mini-open group had two interbody cages placed.

AxiaLIF

The AxiaLIF and AxiaLIF 2 Level Systems were developed by TranS1 and consist of techniques and surgical instruments for creating a pre-sacral access route to perform percutaneous fusion of the L5-S1 or L4-S1 vertebral bodies. The AxiaLIF 2 Level Systems received pre-market notification in April 2008. FDA pre-market notification [Section 510(k)] summaries indicate that the procedures are intended to provide anterior stabilization of the spinal segments as an adjunct to spinal fusion and to assist in the treatment of degeneration of the lumbar disc, performance of lumbar discectomy, and performance of interbody fusion.

There is insufficient evidence to determine whether axial lumbar interbody fusion is as effective or as safe as other established surgical techniques.

Aryan and colleagues (2008) reported on their series of 35 patients, with average follow-up of 17.5 months. These patients had pain secondary to lumbar DDD, degenerative scoliosis, or lytic spondylolisthesis. In 21 of the patients, the AxiaLIF procedure was followed by percutaneous pedicle screw-rod fixation; two patients had extreme lateral interbody fusion combined with posterior instrumentation, and 10 had a stand-alone procedure. Two patients had axial LIF as part of a larger construct, after unfavorable anatomy prevented access to the L5-S1 disc space during open lumbar fusion. Thirty-two patients had radiographic evidence of stable cage placement and fusion at last follow-up.

In 2010, Patil and colleagues reported a retrospective review of 50 patients treated with AxiaLIF. Four patients (8%) underwent two-level AxiaLIF, and 16 patients (32%) underwent a combination of AxiaLIF with another procedure for an additional level of fusion. There were three reoperations due to pseudoarthrosis (n=2) and rectal injury (n=1). Other complications included superficial infection (n=5), hematoma (n=2), and irritation of a nerve root by a screw (n=1). At 12- to 24-month follow-up, VAS scores had decreased from 8.1 to 3.6 (n = 48). At an average 12-month follow-up, 47 of 49 patients (96%) with post-operative radiographs achieved solid fusion. There were no significant differences between pre- and post-operative disk space height and lumbar lordosis angle.

Interspinous Fixation Devices (IFDs)

There is a lack of evidence on the efficacy of IFDs in combination with interbody fusion. One risk is spinous process fracture, while a potential benefit is a reduction in adjacent segment degeneration. Randomized trials with longer follow-up are needed to evaluate the risks and benefits following use of IFDs compared with the established standard (pedicle screw with rod fixation).

## PROFESSIONAL GUIDELINE(S)

In 2014, the North American Spine Society (NASS) issued coverage policy recommendations for the clinical indications for interspinous process fixation devices marketed as an alternative to pedicle screw fixation for lumbar fusion, which was revised in 2019 as follows:

NASS noted that although there is still limited evidence, interspinous fixation with fusion for stabilization may be considered when utilized in the context of lumbar fusion procedures for patients with diagnoses including stenosis, disc herniations, or synovial facet cysts in the lumbar spine, as an adjunct to cyst excision which involves removal of greater than 50 percent of the facet joint and when utilized in conjunction with a robust open laminar and/or facet decortication and fusion, and/or a robust autograft inter- and extra-spinous process decortication and fusion, and/or an interbody fusion of the same motion segment. NASS also noted that no literature supports the use of interspinous fixation without performing an open decortication and fusion of the posterior bony elements or interbody fusion.

In July 2018, the National Institute for Health and Care Excellence (NICE) provided evidence-based recommendations on transaxial interbody lumbosacral fusion for low back pain in adults. The recommendation, based on a literature review conducted in December 2017, states, "Evidence on the safety of transaxial interbody lumbosacral fusion for severe chronic low back pain shows that there are serious but well-recognized complications. Evidence on efficacy is adequate in quality and quantity. Therefore, this procedure may be used provided that standard arrangements are in place for clinical governance, consent and audit. This procedure should only be done by a surgeon with specific training in the procedure, who should carry out their initial procedures with an experienced mentor."

## REGULATORY STATUS

Various instruments used in lumbar spinal fusion have been cleared for marketing by the FDA for specified indications. FDA device approval status can be determined using the following link: https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/index.cfm.

## CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

### CPT Codes

| Code | Description |
|---|---|
| 22586 **(E/I)** | Arthrodesis, pre-sacral interbody technique, including disc preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace |



### HCPCS Codes

| Code | Description |
|---|---|
| No specific codes | |

### ICD10 Codes

| Code | Description |
|---|---|
| Multiple diagnosis codes | |

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## SEARCH TERMS

Not Applicable

## CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Based upon our review, Minimally Invasive/Minimal Access Lumbar Interbody Fusion is not specifically addressed in National or Regional Medicare coverage determinations/policies.

## PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

## POLICY HISTORY/REVISION

**Committee Approval Dates**

08/19/10, 09/15/11, 10/18/12, 09/19/13, 08/21/14, 08/20/15, 07/21/16, 07/20/17, 06/21/18, 07/18/19, 08/20/20, 06/17/21, 06/16/22, 06/22/23, 06/20/24, 06/26/25

| Date | Summary of Changes |
|---|---|
| 06/26/25 | • Annual review, policy guidelines, professional societies and regulatory status sections updated. |
| 01/01/25 | • Summary of changes tracking implemented. |
| 08/20/09 | • Original effective date |