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Medical Policy

Minimally Invasive Lumbar Interbody Fusion

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Policy Number: 617

BCBSA Reference Number: 7.01.115A

Related Policies

- Bone Morphogenetic Protein, #097
- Interspinous Distraction Devices or Spacers, #584
- Facet Arthroplasty, #174
- Image Guided Minimally Invasive Lumbar Decompression IG-MLD for Spinal Stenosis, #240

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Minimally invasive interbody fusion of the lumbar spine may be <u>MEDICALLY NECESSARY</u> using the following approaches:

- Anterior lumbar interbody fusion (ALIF)
- Posterior lumbar interbody fusion (PLIF), or
- Transforaminal lumbar interbody fusion (TLIF).

All other minimally invasive procedures for lumbar interbody fusion are **INVESTIGATIONAL** including, but not limited to:

- Laparoscopic ALIF
- Axial anterior lumbar fusion (AxiaLIF), or
- Lateral interbody fusion (e.g., XLIF, DLIF).

Prior Authorization Information

Commercial Members: Managed Care (HMO and POS)

Prior authorization is **NOT** required.

Commercial Members: PPO, and Indemnity

Prior authorization is **NOT** required.

Medicare Members: HMO BlueSM

Prior authorization is **NOT** required.

Medicare Members: PPO BlueSM

Prior authorization is **NOT** required.

CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

CPT codes:	Code Description
0195T	Arthrodesis, pre-sacral interbody technique, including instrumentation, imaging (when performed), and discectomy to prepare interspace, lumbar; single interspace
0196T	Arthrodesis, pre-sacral interbody technique, including instrumentation, imaging (when performed), and discectomy to prepare interspace, lumbar; each additional interspace (List separately in addition to code for primary procedure)

Description

Percutaneous anterior lumbar fusion (also called 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 while minimizing damage to muscular, ligamentous, neural, and vascular structures. It is performed under fluoroscopic guidance.

A variety of minimally invasive/minimal access procedures are being investigated to perform interbody fusion, with the intent of limiting iatrogenic damage to muscular, ligamentous, neural, and vascular structures. Minimally invasive techniques are being studied for anterior lumbar fusion (ALIF), posterior lumbar interbody fusion (PLIF), and transforaminal lumbar interbody fusion (TLIF).

Anterior Lumbar Interbody Fusion (ALIF)

Anterior access provides direct visualization of the disc space, 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 dural 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 ALIF has also been investigated.

Posterior Lumbar Interbody Fusion (PLIF)

PLIF 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. In minimally invasive PLIF, 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, hypertrophic ligamentum flavum) as well as stabilization of the spine through interbody fusion.

Transforaminal Lumbar Interbody Fusion (TLIF)

TLIF is differentiated from the more traditional bilateral PLIF by a unilateral approach to the disc space through the intervertebral foramen. In minimally invasive TLIF, a single incision about 2-3 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.

Note: This policy does not address other minimally invasive techniques for lumbar fusion, such as extreme lateral interbody fusion (XLIF).

Examples of systems for minimally invasive procedures for lumbar interbody fusion include the AxiaLIF® (Axial Lumbar Interbody Fusion) and AxiaLIF 2 Level systems from TranS1®. All minimally invasive procedures for lumbar interbody fusion are considered investigational regardless of the commercial name, the manufacturer or FDA approval status except as noted in the policy statement.

Summary

Current evidence for some minimally invasive/minimal access approaches includes systematic reviews and non-randomized comparative studies. The available evidence suggests that after an initial training period, short to mid-term health outcomes (including complication and fusion rates, pain and function) following minimally invasive anterior, posterior, and transforaminal approaches are comparable to standard open approaches for single-level interbody fusion of the lumbar spine. Intra and perioperative health outcomes (blood loss and hospital stay) have been shown to be improved. Therefore, the following approaches may be considered **medically necessary** for interbody fusion of the lumbar spine:

Minimally invasive anterior interbody fusion (ALIF)

Minimally invasive posterior lumbar interbody fusion (PLIF)

Minimally invasive transforaminal lumbar interbody fusion (TLIF)

There is insufficient evidence to evaluate the efficacy of ALIF, PLIF, and TLIF for interbody fusion of more than one level of the lumbar spine. Therefore, multi-level lumbar interbody fusion using ALIF, PLIF or TLIF is considered investigational. The available evidence suggests the possibility of an increased risk of complications with laparoscopic ALIF. Therefore, this procedure is considered investigational for lumbar interbody fusion of one or more levels.

There is insufficient published evidence to evaluate whether percutaneous axial lumbar interbody fusion (AxiaLIF) or lateral interbody fusions, which may be called extreme lateral interbody fusion (XLIF) or direct lateral interbody fusion (DLIF), are as effective or as safe as other surgical techniques. In addition, there are a relatively large number of adverse event reports in the MAUDE database for percutaneous

axial lumbar interbody fusion, which raises the possibility of an increased risk of complications. Therefore, lateral interbody fusion and AxiaLIF are considered investigational.

Policy History

Date	Action
11/2011-	Medical policy ICD 10 remediation: Formatting, editing and coding updates.
4/2012	No changes to policy statements.
1/2012	Reviewed - Medical Policy Group - Neurology and Neurosurgery.
	No changes to policy statements.
12/1/2011	New policy, effective 12/1/2011, describing covered and non-covered indications.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:

Medical Policy Terms of Use

Managed Care Guidelines

Indemnity/PPO Guidelines

Clinical Exception Process

Medical Technology Assessment Guidelines

References

- 1. U.S. Food and Drug Administration Center for Devices and Radiological Health. Premarket Notification [510(K)] Summary. TranS1® AxiaLIF® Fixation System. Available at http://www.fda.gov/cdrh/pdf7/K073514.pdf.
- 2. U.S. Food and Drug Administration Center for Devices and Radiological Health. Premarket Notification [510(K)] Summary. TranS1® AxiaLIF® II System. Available at http://www.fda.gov/cdrh/pdf7/K073643.pdf.
- 3. Shen FH, Samartzis D, Dip EB et al. Minimally invasive techniques for lumbar interbody fusion. Orthop Clin N Am 2007: 38:373-86.
- 4. Marotta N, Cosar M, Pimenta L et al. A novel minimally invasive presacral approach and instrumentation technique for anterior L5-S1 intervertebral discectomy and fusion: technical description and case presentations. Neurosurg Focus 2006; 20(1):E9.
- 5. Aryan HE, Newman CB, Gold JJ et al. Percutaneous axial lumbar interbody fusion (AxiaLIF) of the L5-S1 segment: initial clinical and radiographic experience. Minim Invasive Neurosurg 2008; 51(4):225-30.