BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:
Minimally Invasive Lumbar Interbody Fusion

Policy #: 182
Category: Surgery

Latest Review Date: November 2020
Policy Grade: B

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*

    - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
    - *Furnished in a setting appropriate to the patient's medical needs and condition;*
    - *Ordered and furnished by qualified personnel;*
    - *One that meets, but does not exceed, the patient's medical need; and*
    - At least as beneficial as an existing and available medically appropriate alternative.

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Effective for dates of service on or after May 31, 2017:

Blue Advantage will treat **minimally invasive interbody fusion of the lumbar spine** as a **covered benefit** using the following approaches:

- Anterior lumbar interbody fusion (ALIF), or
- Posterior lumbar interbody fusion (PLIF), or
- Transforaminal lumbar interbody fusion (TLIF)
- Lateral interbody fusion (e.g., XLIF, DLIF)

Blue Advantage will treat **all other minimally invasive procedures for lumbar interbody fusion** as a **non-covered benefit and as investigational**, including, but not limited to the following:

- Laparoscopic ALIF
- Axial anterior lumbar fusion (AxiaLIF)

Effective for dates of service on or after July 12, 2011, and prior to May 31, 2017:

Blue Advantage will treat **minimally invasive interbody fusion of the lumbar spine** as a **covered benefit** using the following approaches:

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

Blue Advantage will treat **all other minimally invasive procedures for lumbar interbody fusion** as a **non-covered benefit and as investigational**, including, but not limited to the following:

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

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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), 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).

Interbody fusion of the lumbar spine can be approached from an anterior, lateral, or posterior direction. Anterior or posterior lumbar interbody fusion (ALIF/PLIF) are traditionally performed with an open approach (long incision with wide retraction of the musculature), but can also be performed through minimally invasive/minimal access procedures. Procedures described as minimally invasive range from percutaneous techniques to minimal open access approaches that decrease the size of the incision and reduce muscle retraction. For example, minimally invasive/minimal access PLIF uses tubular retractors (e.g., METRx™, Luxor™) to allow access and open visualization of the surgical area. (PLIF is differentiated from instrumented or noninstrumented posterolateral intertransverse fusion, which fuses the transverse processes alone). Additional minimally invasive approaches that use specialized retractors are lateral transpsoas interbody fusion (LTIF), lateral interbody fusion (e.g., XLIF, DLIF), and transforaminal interbody fusion (TLIF). An axial approach (AxiaLIF), which is performed perpendicular to the long axis of the spine with access through the sacrum, is also being investigated.

Interbody fusion surgeries may also include decompression of the spinal canal, use of interbody cages, bone grafts and osteoinductive agents (e.g., recombinant human bone morphogenetic protein), and insertion of pedicle screws and rods to increase stability of the spine. Minimally invasive procedures may include percutaneous placement of pedicle screws and rods and/or use of bone morphogenetic protein in place of autograft bone harvested from the iliac crest.

Table 1 Open and Minimally Invasive (MI) Approaches to Lumbar Interbody Fusion (LIF)

Procedure	Access	Approach	Visualization
Anterior (ALIF)	Open, MI, or laparoscopic	Transperitoneal or retroperitoneal	Direct, endoscopic or laparoscopic with fluoroscopic guidance
Posterior (PLIF)	Open or MI	Incision centered over spine with laminectomy/laminotomy and retraction of nerve	Direct, endoscopic or microscopic, with fluoroscopic guidance
Transforaminal (TLIF)	Open or MI	Offset from spine, through the intervertebral foramen via unilateral facetectomy	Direct, endoscopic or microscopic, with fluoroscopic guidance
Lateral Extreme lateral (XLIF) Direct lateral (DLIF)	MI	Retroperitoneal through transpsoas	Direct, with neurologic monitoring and fluoroscopic guidance
Para-axial (AxiaLIF®)	MI	Small incision via the pre-sacral space	Indirect, percutaneous, fluoroscopic guidance

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 to 3 cm in length is made approximately 3cm 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.

Lateral Interbody Fusion (e.g., Extreme Lateral Interbody Fusion [XLIF] or Direct Lateral Interbody Fusion [DLIF])
Lateral interbody fusion uses specialized retractors in a minimally invasive, lateral approach to the anterior spine through the psoas. There are several types of these procedures/techniques including, but not limited to, direct lateral interbody fusion (DLIF), extreme lateral interbody fusion (XLIF), and laparoscopic anterior lumbar interbody fusion (LALIF). The aim of lateral interbody fusion in the lumbar spine is to achieve a spinal fusion procedure via a lateral approach in order to avoid the major muscle groups in the back (posterior approach) or the organs and blood vessels in the abdomen (anterior approach). A probe is inserted under fluoroscopic guidance through the psoas muscle, to lie alongside the affected disc, via a lateral approach.

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.

Axial Lumbar Interbody Fusion (AxiaLIF)
Axial lumbosacral interbody fusion (also called pre-sacral, 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.

The procedure for one level axial lumbosacral interbody fusion (axial LIF) is as follows: Under fluoroscopic monitoring, a blunt guide pin introducer is passed through a 15- to 20-mm incision lateral to the coccyx and advanced along the midline of the anterior surface of the sacrum. A guide pin is introduced and tapped into the sacrum. A series of graduated dilators are advanced over the guide pin, and a dilator sheath attached to the last dilator is left in place to serve as a working channel for the passage of instruments. A cannulated drill is passed over the guide pin into the L5-S1 disc space to rest on the inferior endplate of L5. It is followed by cutters alternating with tissue extractors, and the nucleus pulposus is debulked under fluoroscopic guidance. Next, bone graft material is injected to fill the disc space. The threaded rod is placed over the guide pin and advanced through the sacrum into L5. The implant is designed to distract the vertebral bodies and restore disc and neural foramen height. Additional graft material is injected into the rod, where it enters into the disc space through holes in the axial rod. A rod plug is then inserted to fill the cannulation of the axial rod. Percutaneous placement of pedicle or facet screws may be used to provide supplemental fixation. An advantage of axial LIF is that it allows preservation of the annulus and all paraspinous soft tissue structures. However, there is an increased need for fluoroscopy and an inability to address intracanal pathology or visualize the discectomy procedure directly. Complications of the axial approach may include perforation of the bowel and injury to blood vessels and/or nerves.

KEY POINTS:
This policy has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through January 31, 2020.

Summary of Evidence
Current evidence for some minimally invasive/minimal (ALIF, PLIF, TLIF) 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 peri-operative health outcomes (blood loss and hospital stay) have been shown to be improved.

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.

For individuals who have degenerative spine disease at the L4-S1 disc spaces who receive axial lumbosacral interbody fusion (LIF), the evidence includes a comparative systematic review of

case series and 1 retrospective comparative study. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The systematic review found that fusion rates were higher following transforaminal LIF than following axial LIF, although this difference decreased with use of bone morphogenetic protein or pedicle screws. The findings of this systematic review were limited by the lack of prospective comparative studies and differences in how fusion rates were determined. Studies suggest that complication rates may also be increased with 2-level axial LIF. Controlled trials with clinical outcome measures are needed to better define the benefits and risks of this procedure compared with treatment alternatives. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements
North American Spine Society
The North American Spine Society (NASS) published guidelines on the treatment of degenerative spondylolisthesis in 2014. NASS gave a grade B recommendation for surgical decompression with fusion in patients with spinal stenosis and spondylolisthesis. The guidelines discussed posterolateral fusion, 360º fusion, and minimally invasive fusion; it did not address axial lumbosacral interbody fusion.

National Institute for Health and Care Excellence
The U.K.'s National Institute for Health and Clinical Excellence (NICE) provided guidance on transaxial interbody fusion in the lumbosacral spine in 2011. The guidance states that current evidence on the efficacy of transaxial interbody lumbosacral fusion is "limited in quantity but shows symptom relief in the short term in some patients. Evidence on safety shows that there is a risk of rectal perforation." NICE encouraged "further research into transaxial interbody lumbosacral fusion. Research outcomes should include fusion rates, pain and functional scores, quality of life measures, and the frequency of both early and late complications. NICE may review this procedure on publication of further evidence."

In July 2018, the NICE guidance was updated and replaced by 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-recognised 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."

U.S. Preventive Services Task Force Recommendations
The U.S. Preventive Services Task Force has not addressed axial lumbosacral interbody fusion.

KEY WORDS:
Axial anterior lumbar fusion, AxiaLIF, axial lumbar interbody fusion, anterior lumbar interbody fusion, ALIF, posterior lumbar interbody fusion, PLIF, transforaminal lumbar interbody fusion,

TLIF, laparoscopic ALIF, lateral interbody fusion, extreme lateral interbody fusion, XLIF, direct lateral interbody fusion, DLIF, para-axial, pre-sacral interbody fusion, trans-sacral interbody fusion or paracoccygeal interbody fusion, axial LIF, AxiaLIF® system, AxiaLIF II Level system

APPROVED BY GOVERNING BODIES:

The AxiaLIF® (Axial Lumbar Interbody Fusion) and AxiaLIF II Level systems were developed by TranS1® and consist of techniques and surgical instruments to perform percutaneous fusion of the L5-S1 or L4–S1 vertebral bodies. (In 2013, TranS1 acquired Baxano and changed the company name to Baxano Surgical.) U. S. Food and Drug Administration (FDA) premarket notification (510[k]) summaries indicate that the AxiaLIF® (Axial Lumbar Interbody Fusion) and AxiaLIF 2 Level systems 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; to perform lumbar discectomy; or to assist in the performance of interbody fusion. The AxiaLIF® systems are indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, spondylolisthesis (Grade I), or degenerative disc disease, defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. They are not intended to treat severe scoliosis, severe spondylolisthesis (Grades 2, 3, and 4), tumor, or trauma. The devices are not meant to be used in patients with vertebral compression fractures or any other condition in which the mechanical integrity of the vertebral body is compromised. Their usage is limited to anterior supplemental fixation of the lumbar spine at L5-S1 or L4-S1 in conjunction with legally marketed facet or pedicle screw systems.

Other approaches may also use customized instrumentation, and several tubular retractor systems and pedicle screw-rod instrumentation are cleared for marketing through the FDA 510(k) pathway. These include the MAST QUADRANT™ Retractor System, METRx X-tube and Sextant pedicle screw system, all from Medtronic, and the Viper pedicle screw system from DePuy. XLIF uses specialized retractors (MaXcess) and NeuroVision EMG nerve monitoring by NuVasive, while DLIF utilizes specialized instrumentation from Medtronic.

BENEFIT APPLICATION:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, L5-S1 interspace
22899	unlisted procedure, spine

PREVIOUS CODING:

0195T	Arthrodesis, pre-sacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L5-S1 interspace **(Deleted 12/31/18)**
0196T	; L4-L5 interspace (List separately in addition to code for primary procedure) **(Deleted 12/31/18)**
0309T	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft, when performed, lumbar, L4-L5 interspace (List separately in addition to code for primary procedure)

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POLICY HISTORY:

Adopted for Blue Advantage, May 2011
Available for comment May 25 – July 11, 2011
Medical Policy Group, March 2012
Medical Policy Group, November 2012
Medical Policy Group, November 2013
Medical Policy Group, April 2014
Medical Policy Group, February 2015
Medical Policy Group, May 2017
Available for comment July 11 through August 24, 2017
Medical Policy Group, June 2018
Medical Policy Group, December 2018; 2019 CPT Coding Update
Medical Policy Group, November 2020
