

Medical Policy Manual

Topic: Percutaneous Axial Anterior Lumbar Fusion

Date of Origin: June 2007

Section: Surgery

Last Reviewed Date: May 2014

Policy No: 157

Effective Date: August 1, 2014

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Percutaneous axial anterior lumbar interbody fusion (PALIF) is a minimally invasive approach to L4-S1 anterior interbody fusion. Using fluoroscopic guidance, discectomy and bone grafting, followed by insertion of a threaded rod fixation device are performed via a trocar passed through a small incision near the base of the coccyx, upward along the front of the sacrum. This approach may also be referred to as a presacral, trans-sacral, or paracoccygeal anterior LIF or mini-LIF.

Regulatory Status

The devices currently marketed in the United States include the AxiaLIF® Plus (Baxano Surgical, formerly TranS1®, Inc.). This device has received U.S. Food and Drug Administration 510(k) approval for single-level (L5-S1) or two-level (L4-S1) anterior stabilization as an adjunct to spinal fusion.

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

MEDICAL POLICY CRITERIA

Percutaneous axial anterior lumbar interbody fusion is considered **investigational**.

SCIENTIFIC EVIDENCE

The primary beneficial outcomes of interest for treatment of spinal pain are relief of pain and improved function. Both of these outcomes are subjective and can be influenced by nonspecific effects, placebo response, and the variable natural history of the disease. Therefore, evaluating the safety and effectiveness of percutaneous axial anterior lumbar interbody fusion (PALIF) requires data from large, long-term, randomized controlled trials (RCTs) comparing PALIF with conventional open or laparoscopic anterior lumbar fusion techniques. These comparisons are necessary to determine whether any beneficial treatment effects from PALIF provide a significant advantage over conventional spinal fusion techniques. In addition, the rate of adverse events related to complications must be considered in evaluating the net health impact of the various approaches and fusion devices.

Literature Appraisal

There is insufficient evidence to determine whether PALIF provides long-term pain reduction and restoration of function.

Randomized Controlled Trials (RCTs)

There are no randomized controlled trials comparing PALIF with conventional open or laparoscopic anterior lumbar interbody fusion (LIF).

Nonrandomized Trials

Published evidence is limited to small case series, preliminary feasibility studies, and retrospective reviews that do not permit conclusions about the long-term effectiveness or durability of PALIF.^[1-14] These studies had significant methodological limitations including but not limited to the lack of randomized comparison with conventional anterior LIF techniques to control for potential bias, placebo effect, or the natural course of the disease being treated. Further, the small study populations limit the ability to rule out the role of chance as an explanation of study outcomes. In addition, current studies had significant heterogeneity in both patient characteristics, particularly in the level of disease progression, and in surgical techniques such as 1-level PALIF versus non-FDA approved 2-level PALIF.

Adverse Effects

The long-term safety and complication rate for PALIF are unknown compared with other therapies.^[1-5,9,15,16] Studies of adverse events related to PALIF reported inconsistent findings, with some reporting low (e.g., 1.3%)^[17] and some high (e.g., 23.5%)^[18] complication rates. In addition, these studies were limited in quantity and had significant methodological limitations.

The following adverse effects following PALIF have been reported in the published literature:

- Injury to local structures (i.e., bowel, vascular, nerve, ureter)
- Malpositioned screw requiring surgical correction or removal
- Intraoperative breakage of implantation tools (e.g., broken K-wires, sheared pin, cutter fracture)
- Transient intraoperative hypotension
- Foraminal breach with painful compression of nerve root by screw
- Screw migration/subsidence

- Pseudarthrosis (failure to achieve solid fusion)
- Sacral fracture
- Superficial wound and systemic infections
- Osteomyelitis
- Presacral hematoma

Additional details of reported complications can be accessed online in the U.S. Food and Drug Administration (FDA) Manufacturer and User Facility Device Experience (MAUDE) database.^[19]

Clinical Practice Guidelines

There are no evidence-based clinical practice guidelines from U.S. neurosurgery or orthopedic professional associations that recommend PALIF.

Summary

The evidence on percutaneous axial anterior lumbar interbody fusion (PALIF) consists of registry data and a limited number of small nonrandomized observational studies with significant methodological limitations. There is insufficient evidence to determine whether PALIF is as effective or as safe as other surgical techniques or nonsurgical treatment. In addition, long-term durability of treatment effects, and rates of adverse effects and reoperation are not known. Also, there are no clinical practice guidelines from U.S. professional societies that recommend PALIF. Therefore, PALIF is considered investigational.

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CROSS REFERENCES

[Interspinous Fixation \(Fusion\) Devices](#), Surgery, Policy No. 172

[Lumbar Spinal Fusion](#), Surgery, Policy No. 187

CODES	NUMBER	DESCRIPTION
CPT	22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image

CODES	NUMBER	DESCRIPTION
		guidance, includes bone graft when performed, L5-S1 interspace
	0195T	Arthrodesis, pre-sacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L5-S1 interspace
	0196T	; L4-L5 interspace (List separately in addition to code for primary procedure)
	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)
HCPCS	None	