Medicare Advantage Policy Manual **Policy ID:** M-SUR157

Percutaneous Axial Lumbosacral Fusion (LIF)

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Percutaneous axial lumbosacral interbody fusion (LIF; also known as pre-sacral, transsacral, or paracoccygeal interbody fusion) is a minimally invasive technique designed to provide anterior access to the L4-S1 or L5-S1 disc spaces for interbody fusion. This technique minimizes damage to muscular, ligamentous, neural, and vascular structures, and is performed under fluoroscopic guidance.

MEDICARE ADVANTAGE POLICY CRITERIA

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

CMS Coverage Manuals*	None
National Coverage Determinations (NCDs)*	None

Noridian Healthcare Solutions (Noridian) Local Coverage Determinations (LCDs) and Articles (LCAs)*	None
Medical Policy Manual	*Medicare coverage guidance is not available in the health plan's service area for pre-sacral interbody arthrodesis (CPT code 22586 or 22899). Therefore, the health plan's medical policy is applicable.* For ***pre-sacral interbody arthrodesis with instrumentation (CPT 22586 and 22899)***: ✓ Percutaneous Axial Lumbosacral Fusion (LIF), Surgery, Policy No. 157 *(see "NOTE" below)*

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REGULATORY STATUS

The AxiaLIF® and AxiaLIF II Level systems (Quandry Medicare as of 2014) were cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process 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.

These systems are indicated for patients requiring fusion to treat pseudoarthrosis, unsuccessful previous fusion, spinal stenosis, grade 1 or 2 spondylolisthesis, 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 3 and 4), tumor, or trauma. The devices are not meant to be used for 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 the L5-S1 or L4-S1 disc spaces in conjunction with legally marketed facet or pedicle screw systems. *(FDA product code: KWQ.)*

Note, the fact a service or procedure has been issued a CPT/HCPCS code or “is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary." Medicare contractors evaluate services, procedures, drugs or technology to determine if they may be considered Medicare covered services. *(Noridian LCD L35008)*

CROSS REFERENCES

Investigational (Experimental) Services and New and Emerging Medical Technologies and Procedures, Medicine, Policy No. M-149

Interspinous Fixation (Fusion) Devices, Surgery, Policy No. M-172

REFERENCES

None

CODING

NOTE: Prior to January 1, 2019, pre-sacral interbody arthrodesis ***without*** instrumentation was reported with Category III CPT codes 0195T and 0196T and were non-covered according to the Noridian LCD for *Non-Covered Services* (L35008). As of January 1, 2019, there is no longer a specific code available to report pre-sacral interbody arthrodesis ***without*** instrumentation.

Codes	Number	Description
CPT	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
	~~0195T~~	~~Arthrodesis, pre-sacral interbody technique, disc space preparation, discectomy, without instrumentation, with image guidance, includes bone graft when performed; L5-S1 interspace~~ *(Code deleted 01/01/2019)*
	~~0196T~~	~~; L4-L5 interspace (List separately in addition to code for primary procedure)~~ *(Code deleted 01/01/2019)*
HCPCS		

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*