IEHP UM Subcommittee Approved Authorization Guideline			
Guideline	Lumbar Artificial Disk Replacement	**Guideline #**	UM_ORT 05
		Original Effective Date	4/27/2006
Section	Orthopedic	**Revision Date**	8/12/2020

COVERAGE POLICY

Based on review of current coverage practice and medical literature, Lumbar Artificial Disc Replacement is deemed medically appropriate and is a covered service if ALL the following criteria are met:

1. Presence of spondylolisthesis with **1 or more** of the following:
    a. Progressive or severe neurologic deficits (for example, bowel or bladder dysfunction); or
    b. Adults (age greater than 18) who are skeletally mature, with significant and persistent symptoms, despite an adequate trial of conservative care (at least 6 months) with low-grade spondylolisthesis demonstrated on X-ray or MRI; **AND**
2. Degenerative disc disease is limited to the single spinal level at which the disc replacement is planned; **AND**
3. An FDA approved Lumbar Artificial Intervertebral Disc (LAID) device is used in accordance with FDA labeling (including any label requirements regarding the degree of spondylolisthesis); **AND**
4. A single level in the lumbar spine will be treated with an LAID device; **AND**
5. There are no contraindications to lumbar AID device implantation, (including those listed in the FDA labeling), including, but not limited to, the following:
    a. Active systemic infection or infection localized to the site of implantation; or
    b. Osteopenia or osteoporosis (defined as DEXA bone density measured T-score less than -1.0); or
    c. Bony lumbar spinal stenosis; or
    d. Isolated radicular compression syndromes, especially due to disc herniation; or
    e. Pars defect; or
    f. Clinically compromised vertebral bodies at affected level due to current or past trauma; or
    g. Lytic spondylolisthesis or degenerative spondylolisthesis of grade greater than 1 spinal level.

COVERAGE LIMITATIONS AND EXCLUSIONS

Lumbar artificial intervertebral disc (LAID) implantation is considered NOT MEDICALLY NECESSARY for:

1. Adults greater than 60 years of age AND,
2. All other indications not listed above as medically necessary AND,
3. At more than one spinal level is considered not medically necessary AND,

4. Hybrid LAID/Lumbar Fusion (lumbar artificial intervertebral disc at one level at the same time as lumbar fusion at a different level) is considered **not medically necessary**.

ADDITIONAL INFORMATION

Medical problem which has both individual and societal social, economic, and health effects [1]. Conservative treatment including physical therapy, risk factor reduction/modification including weight loss, and medical management may only have limited impact. If conservative management proves unsuccessful or if there is evidence of progressive neurologic nerve damage, surgery with spinal fusion is an appropriate treatment, though still with only limited rate of improvement (Jacobs, et, al 2012).

Lumbar artificial disc replacement or lumbar artificial intervertebral disc replacement (LAID) has been used as an alternative to spinal fusion with the rationale that these devices maintain spinal mobility and may prevent development of adjacent segment pathology (ASP). These devices may have promise for improved patient outcomes or at least non-inferior outcomes with comparable cost. As such, they may be considered medically necessary in carefully selected cases. Caution and careful selection should be used as the current evidence is weak, fails to demonstrate superiority, is heterogeneous due to multiple artificial disc types and is lacking in long term follow up to adequately assess complication rates (Jacobs et al 2012, Wang et al 2012). Because of these serious issues the both providers and institutions performing LAID replacement should exercise prudence and careful monitoring and follow up.

CLINICAL/REGULATORY RESOURCE

A Medicare Decision Memo regarding Lumbar Artificial Disc Replacement states that Lumbar Artificial Disc Replacement (LADR) is not reasonable and necessary for the Medicare population over sixty years of age.

A Medicare National Coverage Determination (NCD) was subsequently issued which states that LADR is not reasonable and necessary for the Medicare population over 60 years of age; therefore, LADR is non-covered for Medicare beneficiaries over 60 years of age.

The Medi-Cal Provider Manual identifies CPT billing codes but provides no clinical guidelines or medical indications.

MCG states that the current role for LADR remains uncertain. Based on review of existing evidence, there are currently no clinical indications for this technology.

Apollo states that artificial intervertebral discs of the lumbar spine are considered investigational.

DEFINITION OF TERMS

Artificial intervertebral disc replacement is an alternative to spinal fusion surgery for selected patients suffering pain due to degenerative disc disease (DDD). The artificial disc was designed to restore normal disc height, to preserve the spinal flexibility as well as decrease degeneration of adjacent discs, which can occur as a result of DDD. (Apollo Managed Care, 2020)

REFERENCES

1. Centers for Medicare & Medicaid Services Decision Memo for Lumbar Artificial Disc Replacement (LADR) (CAG-00292R) May 16, 2006 (CMS) Last updated September 11, 2007. Accessed 7/30/2020.
2. Centers for Medicare & Medicaid Services, National Coverage Determination (NCD) for Lumbar Artificial Disc Replacement 150.10. CMS.gov. Accessed 7/30/2020.
3. Medi-Cal Provider Manual, Surgery: Musculoskeletal System. Accessed 7/30/2020
4. MCG 24th edition, 2020. A-0948 Disk Arthroplasty, Lumbar. Accessed 7/30/2020.
5. Apollo Managed Care 19th edition, 2020. SP 080 Artificial (Prosthetic) Intervertebral Discs and Disc Replacement. Accessed 7/30/2020.
6. Jacobs W, Van Der Gaag NA, Tuschel A, de Kleuver M, Peul W,Verbout AJ, Oner FC. Total disc replacement for chronic back pain in the presence of disc degeneration. Cochrane Database of Systematic Reviews 2012, Issue 9. Art. No.:CD008326. DOI: 10.1003/14651858.CD008326.pub2.
7. Wang, J. C., Arnold, P. M., Hermsmeyer, J. T., & Norvell, D. C. (2012). Do lumbar motion preserving devices reduce the risk of adjacent segment pathology compared with fusion surgery? A systematic review. *Spine, 37,* S133-S143. https://europepmc.org/article/med/22872221

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