



INLAND EMPIRE HEALTH PLAN

IEHP UM Subcommittee Approved Authorization Guidelines
Lumbar Artificial Disc Replacement

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.

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,

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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.

Medicare (2006):

CMS has released a non-coverage determination for the lumbar artificial disc (Last updated September 11, 2007) [6].

Policy: Effective for services performed on or after August 14, 2007, the CMS has found 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 as identified in section 150.10, of Pub.100-03, the NCD Manual.

For Medicare beneficiaries 60 years of age and younger, there is no NCD, leaving such determinations to continue to be made by the local contractors.

Apollo Medical Review Criteria (2013):

The Apollo Review says “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” [7].

The review offers no commentary and sites primarily Aetna and CMS and the U.K.’s NICE report. These sources are cited in this review separately and so are individually referenced.

ECRI Institute (2009):

The ECRI Institute reviewed evidence for the surgery lumbar artificial intervertebral disc replacement (AIDR) using the approved artificial disc devices as of 2007 and again in 2009[8]. The report found that data quality is poor due to failure to analyze the two major trials on an intent to treat basis, small sample size and the availability of multiple implant types which limit interpretation of outcomes and complications. With those qualifications the report states that data suggests that there may be some advantages of AIDR over lumbar spinal fusion. Safety data is inadequate and no data exists on long-term *in vivo* performance of these implants. The report makes no recommendations regarding usage but does provide considerations for hospitals and health plans utilizing this technology.

Aetna Intervertebral Disc Prosthesis (2014):

1. Aetna considers FDA-approved prosthetic intervertebral discs (e.g., MOBI-C, Secure-C Artificial Cervical Disc, the Prestige Cervical Disc, ProDisc-C Total Disc Replacement, Bryan Cervical Disc) medically necessary for the treatment of skeletally mature persons

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with symptomatic (e.g., radicular neck and/or arm pain and/or functional/neurological deficit) cervical degenerative disc disease or herniated disc at one level from C3 to C7, confirmed by radiographic studies (e.g., CT, MRI, x-rays), and who have failed at least 6 weeks of conservative management.

2. Aetna considers lumbar prosthetic intervertebral discs (e.g., the Charite Artificial Disc, and the ProDisc-L Total Disc Replacement) experimental and investigational for lumbosacral degenerative disc disease and for all other indications [9].

Anthem Blue Cross/Blue Shield (2014):

Lumbar Artificial Intervertebral Disc (LAID)[10]

Medically Necessary:

Lumbar artificial intervertebral disc (LAID) implantation is considered medically necessary when ALL of the following are met:

1. 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) with persistent and significant symptoms, despite an adequate trial of at least 6 months of conservative care with low-grade spondylolisthesis demonstrated on x-ray; AND
2. Degenerative disc disease is limited to the single spinal level at which the LAID is planned; AND
3. An FDA approved 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. The individual is skeletally mature; AND
6. 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.

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Not Medically Necessary:

- Lumbar artificial intervertebral disc (LAID) implantation is considered not medically necessary for all other indications not listed above as medically necessary.
- Lumbar artificial intervertebral disc (LAID) implantation at more than one spinal level is considered not medically necessary for all indications.
- 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.

Cochrane Review (2012):

“Although statistically significant, the differences between disc replacement and conventional fusion surgery for degenerative disc disease were not beyond the generally accepted clinical important differences with respect to short-term pain relief, disability and Quality of Life.... Therefore, because we believe that harm and complications may occur after years, we believe that the spine surgery community should be prudent about adopting this technology on a large scale, despite the fact that total disc replacement seems to be effective in treating low-back pain in selected patients, and in the short term is at least equivalent to fusion surgery”[2].

National Institute for Health and Care Excellence (NICE) (United Kingdom) (2009):

1.1 Current evidence on the safety and efficacy of prosthetic intervertebral disc replacement in the lumbar spine is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 A multidisciplinary team with specialist expertise in the treatment of degenerative spine disease should be involved in patient selection for prosthetic intervertebral disc replacement in the lumbar spine. The procedure should only be carried out in patients for whom conservative treatment options have failed or are contraindicated.

1.3 The current evidence includes studies with a maximum follow-up of 13 years, but the majority of evidence is from studies with shorter durations of follow-up. NICE encourages clinicians to continue to collect and publish data on longer-term outcomes, which should include information about patient selection and the need for further surgery [11].

North American Spine Society (2014):

Lumbar Artificial Disc Replacement (disc arthroplasty, disc replacement) is indicated as an alternative to lumbar fusion for patients with discogenic low back pain who meet ALL of the following criteria from the Lumbar Fusion Coverage Recommendation [8]:

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- a) Advanced single level disease noted on MRI and plain radiographs of the Lumbar spine at L4-5 or L5-S1, characterized by moderate to severe degeneration of the disc with Modic changes (defined as peridiscal bone signal above and below the disc space in question) as compared to other normal or mildly degenerative level (characterized by normal plain radiographic appearance and no or mild degeneration on MRI)
- b) Presence of symptoms for at least one year AND that are not responsive to multi-modal nonoperative treatment over that period that should include physical therapy/rehabilitation program but may also include (but not limited to) pain management, injections, cognitive behavior therapy, and active exercise programs.
- c) Absence of active significant psychiatric disorders, such as major depression, requiring pharmaceutical treatment
- d) Primary complaint of axial pain, with possible secondary complaint of lower extremity pain

Patients must also fulfill ALL of the following additional criteria that are unique to artificial disc replacement:

- a) Age 18-60 year old
- b) Absence of significant facet arthropathy at the operative level.

Background:

Chronic low back pain caused by degenerative disc disease (DJD) is a common and difficult 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 [1,2].

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). After review of medical/surgical evidence and current coverage practice, 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. However 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 [2-5]. Because of these serious issues the both providers and institutions performing LAID replacement should exercise prudence and careful monitoring and follow up.

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