

Subject: Lumbar Artificial Disc Replacement

Medical Policy #: 56.0

Status: Review

Original Effective Date: 05-26-2021

Last Annual Review Date: 05-22-2024

Disclaimer

Refer to the member's specific benefit plan and Schedule of Benefits to determine coverage. This may not be a benefit on all plans or the plan may have broader or more limited benefits than those listed in this Medical Policy.

Description

Lumbar artificial disc replacement (LADR) is a surgical procedure used to treat low back pain for degenerative disc disease. The surgical procedure involves a complete removal of the damaged or diseased lumbar intervertebral disc and implant and the degenerative lumbar disc is replaced with an artificial disc. The procedure may be done as an alternative to lumbar spinal fusion and is intended to reduce pain, increase movement at the site of surgery and restore intervertebral disc height.

The use of LADR has been approved for spine arthroplasty in skeletally mature patients with degenerative or discogenic disc disease at one level for L3 to S1. Studies have shown the results of LADR to be at least equivalent to spinal fusion for the treatment of discogenic low back pain. LADR is a technically challenging operation and proper training should be obtained before performing the procedure.

For cervical disc surgery, see Evolent.

Coverage Determination

Prior Authorization is required. Logon to Pres Online to submit a request: <https://ds.phs.org/preslogin/index.jsp>

I. Single-Level Lumbar Artificial Disc Replacement (LADR), (code 22857):

A. Single-Level is covered for Commercial members only.

PHP considers U.S. Food and Drug Administration (FDA)-approved artificial disc replacement (e.g., activL Artificial Disc (L4–S1), Charite Artificial Disc (L4–S1), ProDisc (L4-S1) Total Disc Replacement) medically necessary when **ALL** of the following indications are met:

- The individual is between the ages of 18 to 60
- Documentation demonstrates, degenerative disc disease or significant discogenic back pain with disc degeneration, is confirmed by patient history, physical examination.,
- Imaging confirms absence of significant facet arthropathy at the site of the operative levels
- at least three months of physician-supervised multi-modal conservative management for functionally disabling mechanical low back pain, with ALL of the following:
 - NSAIDs
 - Epidural steroid injections
 - Physical therapy
- Disc reconstruction with the device is performed at single level in the lumbar spine L3-4, L4-L5 or L5-S1, only once in a lifetime, per FDA approved indications. (No history of lumbar disc replacement at any lumbar level).
- Only FDA approved discs (used in accordance with their FDA approved indications/labelling), as listed above.
- Single level lumbar degenerative disc disease has been confirmed by imaging study (eg, MRI or CT), within 6 months.
- Not to be used in combination with a spinal fusion.
- Not to be used for a Planned procedure that includes the use of a lumbar artificial intervertebral disc replacement adjacent to a spinal fusion
- Not to be used in combination with a lumbar stabilization procedure
- Not indicated in the presence of osteopenia or osteoporosis (T-score < -1.0)
- The involved vertebral endplate is appropriate for the dimensions of the implant
- The vertebral bodies at the affected level should not be compromised from trauma
- Not indicated in the presence of ankylosing spondylitis, rheumatoid arthritis, lupus, or other autoimmune disorder
- Not indicated in the presence of isolated radicular compression syndromes due to lumbar disc herniation or bony stenosis

- No prior destabilizing spine surgery of any form at the target level
- Not indicated in the presence of vascular, urological, or other peritoneal or retroperitoneal pathology that may preclude safe and adequate anterior spine exposure as required for the surgery
- Absence of unmanaged significant mental and/or behavioral health disorders (e.g. major depressive disorder, chronic pain syndrome, secondary gain, opioid and alcohol use disorders).
- Absence of contraindications to lumbar artificial disc replacement, including but not limited to:
 - Disease above L3-4; **OR**
 - Active or chronic infection, systemic or local infection to the operative site; **OR**
 - Osteoporosis or osteopenia (DEXA bone mineral density T-score less than or equal to -1.0), or vertebral bodies compromised by disease or prior trauma; **OR**
 - Allergy or sensitivity to implant materials; **OR**
 - Isolated lumbar radiculopathy (especially due to herniated disc), or chronic radiculopathy (unremitting especially leg symptoms lasting over a period of at least 1 year); **OR**
 - Bony lumbar spinal stenosis, or spinal deformity (scoliosis); **OR**
 - Clinically compromised vertebral bodies at the affected level due to current or past disease (eg, ankylosing spondylitis) or trauma (eg, fracture); **OR**
 - Presence of free disc fragment; **OR**
 - Facet ankylosis or joint degeneration; **OR**
 - Involved vertebral endplate dimensionally smaller than 31 mm for activL or 34.5 mm for ProDisc L in the medial lateral and/or 26 mm for activL or 27 mm for ProDisc L in the anterior posterior directions; **OR**
 - Myelopathy; **OR**
 - Pars defect; **OR**
 - Spondylolisthesis greater than Grade 1; **OR**
 - Disc degeneration requiring treatment at more than two levels; **OR**
 - Poorly managed psychiatric disorder

B. Single-Level Artificial Intervertebral Disc Replacement is Non-Covered for Medicaid and Medicare:

PHP follows two CMS guidelines for single-level and multi-level for replacement and revision as not reasonable and necessary.

- Age over 60 yrs old, PHP follows NCD ([150.10](#)) for lumbar artificial disc replacement at single level and multi-level).
- Age 60 years of age and younger, PHP follows LCD ([L37826](#)) for Lumbar artificial disc replacement.

II. Multi-level Lumbar Total Disc Arthroplasty: Replacement (code 22860); Removal (0164T); Revision (0165T) are Non-Covered for Commercial, Medicaid and Medicare:

PHP considers artificial intervertebral disc replacement for the lumbar spine for any indications other than those listed above including, but may not be limited to all of the following (not an all-inclusive list) experimental and investigational because there is insufficient evidence of their effectiveness:

- A. Artificial disc arthroplasty done at more than two spinal levels is experimental.

III. Revision of previous Lumbar Artificial Intervertebral Disc (code 22862):

A. Covered for Commercial members only.

PHP considers the revision or replacement of a lumbar artificial intervertebral disc for the use of FDA-approved lumbar artificial intervertebral disc for replacement at the same level as the previous surgery (one level from L3 to S1. If the need for revision is medically necessary, the following will need to be verified:

- Original surgery was performed with an FDA-approved device (activL, ProDisc L), and in accordance with those approved indications; **AND**
- Documentation as to the reasons for failure of the prior surgery and the potential benefits of the proposed revision surgery, which includes the following:
 - Imaging studies confirm implanted device mechanical failure (eg, dislodgement, implanted device breakage, infection loosening, vertebral body fracture); **AND**
 - Symptoms were relieved by original procedure, but reoccurred upon failure of the implanted device

B. Revision is Non-Covered for Medicaid and Medicare:

PHP follows LCD ([L37826](#)) for revision of previously placed Lumbar Artificial Intervertebral Disc (code 22862 and 0165T), as not reasonable and necessary.

IV. Removal of single level (code 22865) of a Lumbar Artificial Intervertebral Disc:

Covered for Commercial, Medicaid and Medicare on a case-by-case bases.

Though rare and infrequent, PHP recognizes that it maybe medically necessary to remove the artificial disc arthroplasty. If the need to remove disc arthroplasty we require documentation as to the reasons for failure of the prior surgery and the potential benefits of the surgery of the proposed revision surgery.

Coding

The coding listed in this medical policy is for reference only. Covered and non-covered codes are within this list.

CPT Codes	Description
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (List separately in addition to code for primary procedure)

Reviewed by / Approval Signatures

Population Health & Clinical Quality Committee (PHCQC): Gray Clarke MD

Medical Director: Ana Maria Rael MD

Date Approved: May 22,2024

References

1. National Coverage Determination (NCD) for Lumbar Artificial Disc Replacement (LADR) (150.10). [05/01/2024]
2. Local Coverage Determinations (L37826) which follows NCD 150.10- (Not applicable to NM), Revision date 06/17/2021, R2, related Local Coverage Article (A56390), Revision date 01/01/2023, R5. [Cited 05/01/2024]
3. Hayes, Comparative Effectiveness Review of Lumbar Total Disc Replacement for Degenerative Disc Disease, Health Technology Assessment Apr 1, 2019, Annual Review: Mar 24, 2022. [Cited 05/01/2024]
4. Aetna, Intervertebral Disc Prostheses, Number: 0591, Next Review: 06/26/2025. [Cited 05/01/2024]
5. Humana, Artificial Intervertebral Disc Replacement, Review Date: 03/28/2024, Policy Number: HUM-0442-023. [Cited 05/01/2024]
6. Cigna, Intervertebral Disc (IVD) Prostheses: Policy number 0104, Next review Date: 01/15/2025. [Cited 05/01/2024]
7. UHC, Total Artificial Disc Replacement for the Spine, Policy Number: 2024T0437KK, Effective Date: Feb 01, 2024. [Cited 05/01/2024]

Publication History

- 05/24/2023 Original effective date will remain as: 05-26-2021. Reviewed by PHP Medical Policy Committee on 04-19-2023. Policy moved from MPM 36.0. Approved FDA lumbar intervertebral disc for single-level replacement and revision is covered only for Commercial but will continue non-coverage for Medicaid and Medicare. Multi-level Lumbar Total Disc Arthroplasty for: replacement (code 22860); removal (code 0164T); revision (code 0165T) are considered investigational and unproven and therefore NOT COVERED, for Commercial, Medicare, and Medicaid. Removal of single-level LADR (code 22865) is covered for Commercial, Medicaid and Medicare on a case-by-case bases. Previously configured 0164T and 0165T as investigational for all LOB in CY 2021. Newly released in 2023, code 22860 will be config as investigational for ALOB. Previously config codes (22857 and 22862) as investigational for commercial will be removed and will now require PA for Commercial. Previously configured (22857, and 22862) will continue as investigational for Medicare and Medicaid. Previously config codes (22865) as investigational for ALOB will be removed and will now require PA for ALOB. Medicaid and Medicare will follow non-covered guidelines from NCD (150.10) and LCD (L37826/ LCA (A56390), for all levels (single/multi-level).
- 05/22/2024 Annual review. Reviewed by PHP Medical Policy Committee on 05/03/2024 and 06/07/2024. No change. Will keep policy status quo. Codes in section 1B were removed, since it was left there erroneously from previous review. Evolent has removed the information about LADR from their website since it was not part of PHP Utilization Review Matrix 2024.

This Medical Policy is intended to represent clinical guidelines describing medical appropriateness and is developed to assist Presbyterian Health Plan and Presbyterian Insurance Company, Inc. (Presbyterian) Health Services staff and Presbyterian medical directors in determination of coverage. The Medical Policy is not a treatment guide and should not be used as such. For those instances where a member does not meet the criteria described in these guidelines, additional information supporting medical necessity is welcome and may be utilized by the medical director in reviewing the case. Please note that all Presbyterian Medical Policies are available online at: [Click here for Medical Policies](#)

Web links:

At any time during your visit to this policy and find the source material web links has been updated, retired or superseded, PHP is not responsible for the continued viability of websites listed in this policy.

When PHP follows a particular guideline such as LCDs, NCDs, MCG, NCCN etc., for the purposes of determining coverage; it is expected providers maintain or have access to appropriate documentation when requested to support coverage. See the References section to view the source materials used to develop this resource document.