National Imaging Associates, Inc.	
Clinical guidelines: **LUMBAR ARTIFICIAL DISC REPLACEMENT**	**Original Date: June 2021**
CPT Codes:** - **Lumbar Artificial Disc Replacement - Single Level: 22857, 22862, 22865** - **Lumbar Artificial Disc Replacement - Multiple Levels: 22860, 0164T, 0165T** ***See UM Matrix for allowable billed groupings and additional covered codes*	**Last Revised Date: ~~May 2022~~ May 2023**
Guideline Number: NIA_CG_304-1	**Implementation Date: January 2024~~23~~**

GENERAL INFORMATION

It is an expectation that all patients receive care/services from a licensed clinician. All appropriate supporting documentation, including recent pertinent office visit notes, laboratory data, and results of any special testing must be provided. If applicable: All prior relevant imaging results and the reason that alternative imaging cannot be performed must be included in the documentation submitted.

Due to variable outcomes with lumbar artificial disc replacement surgery, individuals should be actively involved in the decision-making process and provided appropriate decision-support materials when considering this intervention.

Lumbar total disc arthroplasty (artificial disc replacement) may be considered **medically necessary** when **ALL** of the following indications are met[1-6]:

- The individual is between the ages of 18 to 60
- Degenerative disc disease or significant discogenic back pain with disc degeneration, is confirmed by documented patient history, physical examination, and key radiographic studies, with no more than Grade 1 (low level) spondylolisthesis demonstrated on x-ray at the operative levels
- Imaging confirms absence of significant facet arthropathy at operative levels

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- At least six months of non-operative (conservative) treatment have failed to resolve symptoms (see ***Note**)
- Disc reconstruction with the device is performed at one or two consecutive levels in the lumbar spine from L3-S1 using an anterior retroperitoneal approach
- The device used as the disc replacement device is FDA-approved for lumbar disc replacement and is used in accordance with FDA labelling
- There are no contraindications to lumbar artificial disc replacement, including but not limited to (see ****Note**):
    - Disease above L3-4
    - Active systemic or local infection
    - Osteoporosis or osteopenia (DXA bone mineral density T-score less than or equal to -1.0), or vertebral bodies compromised by disease or prior trauma
    - Allergy or sensitivity to implant materials
    - Isolated lumbar radiculopathy (especially due to herniated disc), or chronic radiculopathy (unremitting especially leg symptoms lasting over 1 year)
    - Spinal stenosis, or spinal deformity (scoliosis)
    - Spondylolisthesis greater than Grade 1
    - Disc degeneration requiring treatment at more than two levels
    - Severe facet arthrosis or joint degeneration
    - Presence of free disc fragment
    - Poorly managed psychiatric disorder

Artificial lumbar disc replacement is considered **not medically necessary** in all other circumstances, including artificial disc arthroplasty done at more than two spinal levels, and hybrid (combination artificial disc and fusion) procedures.

***NOTE**: Conservative care is focused multi-modal nonoperative treatment that must include a physical therapy/rehabilitation program with cognitive-behavioral components. Treatment may also include pain management injections and active exercise programs. This must be clearly outlined in the medical record.

****NOTE**: Contraindications are related to the levels being considered for surgery.

RELATIVE CONTRAINDICATIONS FOR SPINE SURGERY (NOTE: Cases may not be approved if the below contraindications exist):

- **Medical contraindications** to surgery (e.g., severe osteoporosis; infection of soft tissue adjacent to the spine and may be at risk for spreading to the spine; severe cardiopulmonary disease; anemia; malnutrition and systemic infection)[7, 8]
- **Psychosocial risk factors**. It is imperative to rule out non-physiologic modifiers of pain presentation or non-operative conditions mimicking radiculopathy or instability (e.g., peripheral neuropathy, piriformis syndrome, myofascial pain, sympathetically mediated

pain syndromes, sacroiliac dysfunction, psychological conditions, etc.) prior to consideration of elective surgical intervention.[9] Individuals with clinically significant depression or other psychiatric disorders being considered for elective spine surgery will be reviewed on a case-by-case basis and the surgery may be denied for risk of failure

- **Morbid Obesity**. Contraindication to surgery in cases where there is significant risk and concern for improper post-operative healing, post-operative complications related to morbid obesity, and/or an inability to participate in post-operative rehabilitation.[10] These cases will be reviewed on a case-by-case basis and may be denied given the risk of failure

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OVERVIEW

- All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests and must be performed by surgeons with appropriate training (neurosurgery, orthopedic surgery). A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic condition(s). A failure of accurate correlation may be an indication for denial of cases. It is imperative to rule out non-physiologic modifiers of pain presentation or non-operative conditions (e.g., peripheral neuropathy, piriformis syndrome, myofascial pain, sympathetically mediated pain syndromes, psychological conditions, etc.) prior to consideration of elective surgical intervention.
- Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions.
    - Individuals being considered for surgical intervention should first undergo a comprehensive neuro-musculoskeletal examination to identify mechanical pain generators that may respond to non-surgical techniques or may be refractory to surgical intervention
    - While sufficient time allowances for non-operative treatment are required to determine the natural cause and response to non-operative treatment of low back pain disorders, timely decision making for operative intervention is critical to avoid de-conditioning and increased disability
- In general, if the program of non-operative treatment fails, operative treatment is indicated when:
    - Improvement of the symptoms has plateaued or failed to occur, and the residual symptoms of pain and functional disability are unacceptable at the end of 6 months of active treatment, or at the end of longer duration of non-operative programs for debilitated individuals with complex problems; and/or
    - Frequent recurrences of symptoms cause serious functional limitations even if a non-operative active treatment program provides satisfactory relief of symptoms, and restoration of function on each recurrence

- **Claims Billing & Coding:**
  - NIA uses a combination of internally developed edits in addition to an enhanced set of industry standard editing. NIA's Claims Edit Module is a group of system edits that run multiple times per day. Edits that are part of this module include industry standard edits that apply to spine surgery services and NIA custom edits developed specifically for spine surgery. The following describes each of the edits NIA applies:
- **Outpatient Code Editor (OCE):** This edit performs all functions that require specific reference to HCPCS codes, HCPCS modifiers, and ICD-9-CM diagnosis codes. The OCE only functions on a single claim and does not have any cross-claim capabilities. NIA is consistent with CMS.
- **National Correct Coding Initiative (NCCI) editing**: The edit prevents improper payment when incorrect code combinations are reported. The NCCI contains two tables of edits. The Column One/Column Two Correct Coding Edits table and the Mutually Exclusive Edits table include code pairs that should not be reported together for a number of reasons explained in the Coding Policy Manual. NIA is consistent with CMS.
  - Incidental edits: This edit applies if a procedure being billed is a component of another procedure that occurred on the same date of service for the same provider and tax ID and claimant
  - Mutually exclusive editing: This edit applies if a procedure being billed is mutually exclusive with a procedure that occurred on the same date of service for the same provider tax ID and claimant
- **Multiple Procedure Discounts (MPD):** This edit applies a reduction to the second and any other subsequent services by the same provider, in the same setting, for the same member. We typically apply a 50% reduction. NIA follows the CMS methodology that began in January 2011 which allows for application of MPD to codes within CMS's two specific advanced imaging code families. However, NIA differs from CMS in that we apply MPD to all provider types unless health plan contracts prohibit this.

POLICY HISTORY

Date	Summary
2023	
November 2022	CPT code revision – removed 0163T, added 22860
May 2022	No changes
June 2021	Independent LADR guideline created from lumbar spine surgery guideline

REFERENCES

1. Jacobs WC, van der Gaag NA, Kruyt MC, et al. Total disc replacement for chronic discogenic low back pain: a Cochrane review. *Spine (Phila Pa 1976)*. Jan 1 2013;38(1):24-36. doi:10.1097/BRS.0b013e3182741b21
2. Radcliff K, Spivak J, Darden B, 2nd, Janssen M, Bernard T, Zigler J. Five-Year Reoperation Rates of 2-Level Lumbar Total Disk Replacement Versus Fusion: Results of a Prospective, Randomized Clinical Trial. *Clin Spine Surg*. Feb 2018;31(1):37-42. doi:10.1097/bsd.0000000000000476
3. Zigler JE, Delamarter RB. Five-year results of the prospective, randomized, multicenter, Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential arthrodesis for the treatment of single-level degenerative disc disease. *J Neurosurg Spine*. Dec 2012;17(6):493-501. doi:10.3171/2012.9.Spine11498
4. Zigler J, Gornet MF, Ferko N, Cameron C, Schranck FW, Patel L. Comparison of Lumbar Total Disc Replacement With Surgical Spinal Fusion for the Treatment of Single-Level Degenerative Disc Disease: A Meta-Analysis of 5-Year Outcomes From Randomized Controlled Trials. *Global Spine J*. Jun 2018;8(4):413-423. doi:10.1177/2192568217737317
5. Coverage policy recommendation: lumbar artificial disc replacement. North American Spine Society (NASS). Updated February 2019. https://www.spine.org/coverage
6. Li YZ, Sun P, Chen D, Tang L, Chen CH, Wu AM. Artificial Total Disc Replacement Versus Fusion for Lumbar Degenerative Disc Disease: An Update Systematic Review and Meta-Analysis. *Turk Neurosurg*. 2020;30(1):1-10. doi:10.5137/1019-5149.Jtn.24799-18.2
7. Puvanesarajah V, Shen FH, Cancienne JM, et al. Risk factors for revision surgery following primary adult spinal deformity surgery in patients 65 years and older. *J Neurosurg Spine*. Oct 2016;25(4):486-493. doi:10.3171/2016.2.Spine151345
8. Varshneya K, Jokhai RT, Fatemi P, et al. Predictors of 2-year reoperation in Medicare patients undergoing primary thoracolumbar deformity surgery. *J Neurosurg Spine*. Jul 24 2020:1-5. doi:10.3171/2020.5.Spine191425
9. Kreiner DS, Hwang SW, Easa JE, et al. An evidence-based clinical guideline for the diagnosis and treatment of lumbar disc herniation with radiculopathy. *Spine J*. Jan 2014;14(1):180-91. doi:10.1016/j.spinee.2013.08.003
10. Epstein NE. High lumbar noninstrumented fusion rates using lamina autograft and Nanoss/bone marrow aspirate. *Surg Neurol Int*. 2017;8:153. doi:10.4103/sni.sni_248_17

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Reviewed / Approved by NIA Clinical Guideline Committee

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