*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: December ~~May~~ 2023**
Guideline Number: NIA_CG_304-1	**Implementation Date: July 2~~January 2~~024**

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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.

STATEMENT

Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions. All operative interventions must be based on a positive correlation with clinical findings, the natural history of the disease, the clinical course, and diagnostic tests or imaging results. All individuals being considered for surgical intervention should receive a comprehensive neuromusculoskeletal examination to identify pain generators that may either respond to non-surgical techniques or may be refractory to surgical intervention.~~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.~~

Because of variable outcomes with surgery, individuals should be actively involved in the decision-making process and provided appropriate decision-support materials explaining potential risks/benefits and treatment alternatives when considering this intervention.

Scope

Spinal surgeries should be performed only by those with extensive surgical training (neurosurgery, orthopedic surgery). Choice of surgical approach is based on anatomy, pathology, and the surgeon's experience and preference.

Instrumentation, bone formation or grafting materials, including biologics, should be used at the surgeon’s discretion; however, use should be limited to FDA approved indications regarding the specific devices or biologics.

See LEGISLATIVE REQUIREMENTS for specific mandates in the State of Washington

INDICATIONS~~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, 2]~~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
- At least six months of non-operative (conservative) treatment have failed to resolve symptoms ~~(see ***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.
    - 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.
        -
- 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

CONTRAINDICATIONS

- ~~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) [3, 4][~~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 [5].[~~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 [6, 7].~~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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LEGISLATIVE LANGUAGE

Washington

Washington State Health Care Authority: Health Technology Clinical Committee
20170120B – Artificial disc replacement – Re-review [8]

HTCC coverage determination:
Lumbar artificial disc replacement is **not a covered benefit.**

~~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~~

POLICY HISTORY

Date	Summary
December 2023	• Added legislative language for WA state
May 2023	Updated References
November 2022	CPT code revision – removed 0163T, added 22860
May 2022	No changes

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Reviewed / Approved by NIA Clinical Guideline Committee

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