

Evolut Clinical Guideline 1765 for Lumbar Artificial Disc Replacement

Guideline or Policy Number: Evolent_CG_ <u>1765</u> 304-4	<u>Applicable Codes</u>	
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Original Date: June 2021	Last Revised Date: -December <u>2023</u>November 2024	Implementation Date: July 2024 <u>2025</u>

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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.

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.

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.

Scope

Spinal surgeries should be performed only by those with extensive and specialized 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.

Special Note

See Legislative Language for specific mandates in the State of Washington

INDICATIONS

Lumbar total disc arthroplasty (artificial disc replacement) may be considered **medically necessary** when **ALL** of the following indications are met ^(1,2):

- 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
 - **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 ⁽³⁾

- 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.

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) ^(4,5,6)

- **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. ^(6,7) 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.
- **Active Tobacco or Nicotine use. Nicotine inhibits spinal fusion, and although spinal fusion is not performed during lumbar disc replacement, nicotine use is associated with increased rates of axial low back pain.** ^(8,9) **Accordingly, individuals must be free from smoking and/or nicotine use for at least six weeks prior to surgery and during the entire period of fusion healing.** ^(10,11)
- **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. ^(12,13) These cases will be reviewed on a case-by-case basis and may be denied given the risk of failure.

LEGISLATIVE LANGUAGE

Washington

20170120B – Artificial Disc Replacement – Re-review ⁽¹⁴⁾

Washington State Health Care Authority

Health Technology Clinical Committee

Final Findings and Decision

HTCC coverage determination:

Lumbar artificial disc replacement is **not a covered benefit**.

Cervical artificial disc replacement is a covered benefit with conditions, consistent with the criteria identified in the reimbursement determination.

HTCC reimbursement determination:

Limitations of coverage:

Patients must meet FDA approved indications for use and not have any contraindications. FDA approval is device specific but includes:

- Skeletally mature patients
- Disc replacement following one- or two-level discectomy for intractable symptomatic radiculopathy or myelopathy confirmed by patient findings and imaging.

Patients must have advanced imaging and clinical evidence of corresponding nerve root or spinal cord compression and have failed or be inappropriate for non-operative care. For

two-level procedures, objective evidence of radiculopathy, myelopathy or spinal cord compression at two consecutive levels is required.

Non-covered indicators: NA

CODING AND STANDARDS

Coding

CPT Codes

- Lumbar Artificial Disc Replacement - Single Level: 22857, 22862, 22865
- Lumbar Artificial Disc Replacement - Multiple Levels: 22860, ±0164T, ±0165T

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

POLICY HISTORY

Date	Summary
<u>November 2024</u>	<ul style="list-style-type: none"> • <u>This guideline replaces Evolent Clinical Guideline 304-1 for Lumbar Artificial Disc Replacement</u> • <u>Updated guideline formatting to Evolent standard</u> • <u>Added the '+' sign before CPT codes +0164T and +0165T for alignment with the Evolent Matrix</u> • <u>Removed the word 'severe' before osteoporosis as a relative contraindication</u> • <u>Clarified language regarding nicotine use prior to lumbar artificial disc replacement in the Relative Contraindications section</u> • <u>Updated references</u>
December 2023	<ul style="list-style-type: none"> • Added legislative language for WA state

Date	Summary
May 2023	<ul style="list-style-type: none">• Updated references

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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1. Zigler J, Delamarter R. 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*. 2012; 17: 493-501. 10.3171/2012.9.Spine11498.
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14. Washington State Health Care Authority. Artificial disc replacement-Re-review [Adopted March 17, 2017]. Washington State Health Care Authority. 2008; Accessed: September 23, 2024. www.hca.wa.gov/assets/program/adr-rr-final-findings-decision-20170317.pdf.

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CODING AND STANDARDS

Coding

CPT Codes

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- **Lumbar Artificial Disc Replacement - Multiple Levels:** 22860, +0164T, +0165T

Applicable Lines of Business

<input checked="" type="checkbox"/>	CHIP (Children's Health Insurance Program)
<input checked="" type="checkbox"/>	Commercial
<input checked="" type="checkbox"/>	Exchange/Marketplace
<input checked="" type="checkbox"/>	Medicaid
<input checked="" type="checkbox"/>	Medicare Advantage

POLICY HISTORY

Date	Summary
November 2024	<ul style="list-style-type: none"> • This guideline replaces Evolent Clinical Guideline 304-1 for Lumbar Artificial Disc Replacement • Updated guideline formatting to Evolent standard • Added the '+' sign before CPT codes +0164T and +0165T for alignment with the Evolent Matrix • Removed the word 'severe' before osteoporosis as a relative contraindication • Clarified language regarding nicotine use prior to lumbar artificial disc replacement in the Relative Contraindications section • Updated references
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Date	Summary
May 2023	<ul style="list-style-type: none">• Updated references

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. A list of procedure codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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