

Cigna Medical Coverage Policies – Musculoskeletal Lumbar Total Disc Arthroplasty

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Instructions for use

The following coverage policy applies to health benefit plans administered by Cigna. Coverage policies are intended to provide guidance in interpreting certain standard Cigna benefit plans and are used by medical directors and other health care professionals in making medical necessity and other coverage determinations. Please note the terms of a customer's particular benefit plan document may differ significantly from the standard benefit plans upon which these coverage policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a coverage policy.

In the event of a conflict, a customer's benefit plan document always supersedes the information in the coverage policy. In the absence of federal or state coverage mandates, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of:

1. The terms of the applicable benefit plan document in effect on the date of service
2. Any applicable laws and regulations
3. Any relevant collateral source materials including coverage policies
4. The specific facts of the particular situation

Coverage policies relate exclusively to the administration of health benefit plans. Coverage policies are not recommendations for treatment and should never be used as treatment guidelines.

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CMM-610: Lumbar Total Disc Arthroplasty
CMM-610.1: General Guidelines
CMM-610.2: Initial Primary Lumbar Total Disc Arthroplasty
CMM-610.3: Failed Lumbar Total Disc Arthroplasty Implant
CMM-610.4: Non-Indications
Codes (CMM-610)
Evidence Discussion (CMM-610)
References (CMM-610)

CMM-610.1: General Guidelines

Application of Guideline

- The determination of medical necessity for the performance of lumbar total disc arthroplasty is always made on a case-by-case basis.
- For additional timing and documentation requirements, see **CMM-600.1: Prior Authorization Requirements**.

CMM-610.2: Initial Primary Lumbar Total Disc Arthroplasty

Initial primary lumbar total disc arthroplasty is considered **medically necessary** when **ALL** of the following criteria have been met:

- Individual is age 18 to 60 years old
- Lumbar disc prosthesis approved by the FDA or for an FDA approved indication and in accordance with FDA labeling
- No planned simultaneous fusion (hybrid surgery) at an adjacent lumbar level
- The planned implant will be used in the reconstruction of a **single-level** lumbar disc at only one of the following lumbar levels: L3-4, L4-L5, or L5-S1
- Absence of facet ankylosis or severe facet degeneration at the operative level
- Plain X-rays **and** advanced diagnostic imaging studies (i.e., CT, MRI) confirm **ALL** of the following:
 - ◆ **Presence** of moderate to severe **single-level** disc degeneration at the operative level (between L3-L4, L4-L5, or L5-S1)
 - ◆ **Absence** of degenerative disc disease at **more than one level** (between L3-L4, L4-L5, or L5-S1)
 - ◆ **Absence** of degenerative disc disease above L3-L4
- Subjective symptoms (concordant with **single-level** degenerative lumbar disc disease [DDD]) include significant level of pain on a daily basis defined as clinically significant functional impairment (e.g., inability to perform household chores, prolonged standing, etc.)

- Structured physician-supervised, multi-modal, nonoperative management of medical care with licensed healthcare professionals which includes **ALL** of the following:
 - ◆ Regularly scheduled appointments
 - ◆ Follow-up evaluation
 - ◆ Less than clinically meaningful improvement with **BOTH** of the following for **at least six (6) consecutive months** (unless contraindicated):
 - Prescription strength analgesics, steroids, gabapentinoids, and/or NSAIDs
 - Provider-directed exercise program prescribed by a physical therapist, chiropractic provider, osteopathic or allopathic physician
- 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)

CMM-610.3: Failed Lumbar Total Disc Arthroplasty Implant

For a revision of a failed lumbar total disc arthroplasty to a lumbar fusion, see **CMM-609.7: Lumbar Fusion (with or without Decompression) Following Failed Lumbar Disc Arthroplasty Surgery**

CMM-610.4: Non-Indications

Not Medically Necessary

- Lumbar total disc arthroplasty performed without meeting the requirements listed in the **General Guidelines** and the criteria in the procedure-specific section (initial disc arthroplasty) is considered **not medically necessary**.
- Lumbar total disc arthroplasty is considered **not medically necessary** when performed for **ANY** of the following:
 - ◆ Lumbar partial disc prosthetics
 - ◆ As an adjunct to the treatment of primary-central or far-lateral disc herniation
- Lumbar total disc arthroplasty is considered **not medically necessary** for **ANY** of the following **contraindications**:
 - ◆ Performed for the revision of a failed lumbar artificial total disc arthroplasty
 - ◆ The individual has osteopenia or osteoporosis (T-score < -1.0)
 - ◆ There is evidence on imaging studies of **ANY** of the following:
 - Degenerative or lytic spondylolisthesis >3mm
 - Lumbar spinal stenosis
 - Pars interarticularis defect with either spondylolysis or isthmic spondylolisthesis
 - Lumbar scoliosis (>11 degrees of sagittal plane deformity)
 - Spinal fracture
 - Infection
 - Presence of tumor or active infection at the site of implantation
 - Lumbar nerve root compression or bony spinal stenosis

- Preoperative remaining disc height <3mm
- Mid-sagittal stenosis of <8mm (by MRI)
- ◆ History of ankylosing spondylitis, rheumatoid arthritis, lupus, or other autoimmune disorder
- ◆ Allergy or sensitivity to implant materials
- ◆ Isolated radicular compression syndromes especially due to lumbar disc herniation
- ◆ Involved vertebral endplate is dimensionally smaller than the approximate dimensions of the implant in anterior/posterior width and lateral width
- ◆ Clinically compromised vertebral bodies at the affected level due to current or past trauma

Codes (CMM-610)

The inclusion of any code in this table does not imply that the code is under management or requires prior authorization. Refer to the applicable health plan for management details. Prior authorization of a code listed in this table is not a guarantee of payment. The Certificate of Coverage or Evidence of Coverage policy outlines the terms and conditions of the member's health insurance policy.

Code	Code Description/Definitions
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), 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)
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
+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)

Evidence Discussion (CMM-610)

Lumbar Total Disc Arthroplasty

Artificial disc replacement is indicated for discogenic low back pain with single level lumbar disc disease at L3-L4, L4-L5, or L5-S1 in individuals who have axial pain and possibly radicular pain and who have failed six (6) months or more of non-surgical medical management and who do not have any unmanaged mental or behavioral health disorders. It should be noted that multiple studies and reports have shown most cases of back pain and sciatica are self-limited and typically improve within with conservative care.

Risks/complications of lumbar total disc replacement surgery are similar to anterior lumbar fusion and include, but are not limited to, the following: infection; hematoma; persistent or incomplete relief of symptoms; possible need for more surgery; ureteral injury; retrograde ejaculation; ileus; neurovascular injury; deep vein thrombosis; pulmonary embolus; and, death. Complications related to the implant (e.g., device dislocation, subsidence, osteolysis from wear debris) are also possible. Overall complications rates of TDA are less than fusion.

Despite potential complications, there are numerous studies reporting superior results with TDA versus lumbar fusion, including pain scores and shorter operative times and hospitalization. As noted in the 2019 North American Spine Society (NASS) *Coverage Policy Recommendations: Lumbar Artificial Disc Replacement*, contraindications to lumbar disc arthroplasty include the following: degenerative disc disease at multiple levels; spinal instability/spondylolisthesis greater than Grade I; chronic radiculopathy; osteopenia; poorly managed psychiatric disorder; significant facet arthropathy at the same level; age < 18 yrs. or > 60 yrs.; infection; and, tumor.

Jackson et al. (2020) noted higher rates of postoperative complications and worse functional outcomes in individuals with psychological disorders undergoing spinal surgery. It was concluded that proper identification and treatment of these conditions prior to surgery may significantly improve many outcome measures in this population.

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