

The Department of Vermont Health Access Clinical Criteria

Subject: Total Artificial Cervical Disc Replacement of the Spine

Last Review: January 11, 2023*

Past Revisions: N/A

***Please note: Most current content changes will be highlighted in yellow.**

Description of Service or Procedure

An artificial disc is a prosthetic device designed to maintain motion in the treated vertebral segment. An artificial disc essentially functions like a joint, allowing for flexion, extension, side bending and rotation. Artificial disc replacement (ADR) surgery is a type of joint replacement procedure, or arthroplasty, which involves inserting an artificial disc into the intervertebral space after a natural disc has been removed. The artificial disc is intended to relieve pain, restore disc height, maintain motion of the natural spine, and prevent degeneration of adjacent discs.

Disclaimer

Coverage is limited to that outlined in Medicaid Rule or Health Care Administrative Rules that pertains to the member's aid category. Prior Authorization (PA) is only valid if the member is eligible for the applicable item or service on the date of service.

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at <https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules>

| | |
|--------|--|
| 7102.2 | Prior Authorization Determination |
| 4.101 | Medical Necessity for Covered Services |
| 4.104 | Medicaid Non-Covered Services |

Coverage Position

ADR may be covered for members:

- When the device is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont Office of Professional Regulation's website*, Statute, or rule who is knowledgeable regarding ADR and who provides medical care to the member AND
- When the clinical criteria below are met.

* Vermont's Office of Professional Regulation's website: <https://sos.vermont.gov/opr/>



Coverage Criteria

The DVHA will follow **Medicare AND InterQual®** criteria for Cervical Artificial Disc Replacement. Prior Authorization is required.

Artificial Cervical Disc Replacement (CDR) C3-C7 may be considered medically necessary when **all** following criteria are met:

- Age greater than or equal to 18 and less than or equal to 60
- The device is FDA approved; AND
- Member must be skeletally mature; AND
 1. The member has EITHER
 - a. Intractable cervical radicular pain or myelopathy which has failed at least 6 weeks of conservative non-operative treatment including physician-directed pain management (e.g., pharmacotherapy addressing neuropathic pain and physical therapy) OR
 - b. Member has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical intervention, AND
 2. The member must have clinical evidence of corresponding nerve root or spinal cord compression documented by computed tomography (CT), myelography, or magnetic resonance imaging (MRI), AND
 3. Cervical degenerative disc disease (CDDD) between C3 to C7, AND
 4. The member is free from absolute contraindications to cervical disc replacement (CDR) which include:
 - a. Extreme obesity (BMI \geq 40 kg/m²)
 - b. Significant cervical anatomical deformity
 - c. Allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)
 - d. Active systemic infection or infection at the operating site
 - e. Osteoporosis or osteopenia
 - f. Marked cervical instability on resting lateral or flexion/extension radiographs demonstrated by translation greater than 3.5mm, and/or greater than 11° angular difference to that of either level adjacent the treated level
 - g. Severe spondylosis
 - h. Clinically compromised vertebral bodies at the affected level
 - i. Prior fusion at the adjacent level
 - j. Prior surgery at treated level
 5. Two-level procedures performed simultaneously may be considered reasonable and necessary if there is objective clinical evidence of radiculopathy, myelopathy or spinal cord compression at two corresponding contiguous levels. A CDR device FDA-approved for 2 levels is required. (i.e., Mobi-C, Prestige LP).

Cervical Disc Replacement Medicare Coverage Determination L38033

<https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38033&ver=11&>

Cervical Disc Replacement Devices:

M6-C™ Artificial Cervical Disc Prosthesis

M6-C™ Artificial Cervical Disc Prosthesis

Mobi-C® Cervical Disc Prosthesis (two-level)

ProDisc-C® Total Disc Replacement
Prestige® LP Cervical Disc (two level)
Prestige® Cervical Disc System
Bryan® Cervical Disc
SECURE®-C Artificial Cervical Disc
PCM® Cervical Disc System
The Simplify® Cervical Artificial Disc (two level)

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence-based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical criteria for repeat service or procedure

See below – revision is covered.

Type of service or procedure covered

Cervical disc replacement, revision and removal is covered when medically necessary.

Type of service or procedure not covered (this list may not be all inclusive)

Cervical disc arthroplasty is considered INVESTIGATIONAL for the following:

- Disc replacement at 2 non-contiguous levels or 3 or more levels
- Combined use of an artificial cervical disc and fusion
- Prior surgery at the treated level
- Previous fusion at another level
- Any anatomical deformity (e.g. ankylosing spondylitis, trauma)
- Any autoimmune disease or rheumatoid arthritis
- Moderate to severe facet joint arthropathy at the involved level
- Metabolic bone disease (e.g. osteoporosis, Paget's disease, osteomalacia, osteogenesis imperfecta) or taking medications known to potentially interfere with bone/soft tissue healing (e.g. steroids)
- Malignancy
- Chronic renal failure
- Non-FDA approved cervical disc devices
- In alignment with CMS, lumbar artificial disc replacement is not covered. See Medicare LCD L37826 at <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37826&ver=21>

Coding guidelines

CPT Codes:

- 22856- Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical
- 22858- Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophylectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (list separately in addition to code for primary procedure)
- 22861-Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
- 22864-Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
- 0095T-Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)
- 0098T-Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)

ICD-10 PCS Codes:

- 0RR30JZ-REPLACEMENT OF CERV DISC WITH SYNTH SUB, OPEN APPROACH
- 0RW30JZ-REVISION OF SYNTHETIC SUBSTITUTE IN CERV DISC, OPEN APPROACH
- 0RP30JZ-REMOVAL OF SYNTH SUB FROM CERV DISC, OPEN APPROACH

ICD-10 Diagnosis codes CERVICAL disc:

| | |
|---------|---------|
| G54.2 | M50.21 |
| G54.9 | M50.221 |
| M48.02 | M50.223 |
| M50.01 | M50.31 |
| M50.021 | M50.321 |
| M50.022 | M50.322 |
| M50.023 | M50.322 |
| M50.11 | M50.323 |
| M50.121 | M51 |
| M50.122 | M51.2 |
| M50.123 | M53.1 |

Medicare Billing and Coding Local Coverage Article A57021

<https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=57021&ver=10&=>

References

Centers for Medicare and Medicaid Services. (2022, January 1). *Local coverage article (LCA) Medicare billing and coding A57021*. Medicare Coverage Database. Retrieved December 29, 2022, from <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleid=57021&ver=10&=>

Centers for Medicare and Medicaid Services. (2022, July 21). *Local coverage determination (LCD) cervical disc replacement L38033*. Medicare Coverage Database. Retrieved December 29, 2022, from <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=38033&ver=11>

Centers for Medicare and Medicaid Services. (2021, June 17). *Local coverage determination (LCD) lumbar artificial disc replacement L37826*. Medicare Coverage Database. Retrieved December 29, 2022, from <https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37826&ver=21>

Centers for Medicare and Medicaid Services. (n.d). *Early and periodic screening, diagnostic, and treatment*. Medicaid.gov. <https://www.medicaid.gov/medicaid/benefits/epsdt/index.html>

Hellum, C., Berg, L., Gjertsen, O., Neckelmann, G., Storheim, K., Keller, A. Grundnes, O., & Espeland, A. (2012). Adjacent level degeneration and facet arthropathy after disc prosthesis surgery or rehabilitation in patients with chronic low back pain and degenerative disc: Second report of a randomized study. *Spine* 37(25), 2063-2073. doi: 10.1097/BRS.0b013e318263cc46

National Institute for Health and Care Excellence (NICE). (2020, December 11). *Low back pain and sciatica in over 16s: Assessment and management*. NICE Guideline 59. Retrieved December 29, 2022, from <https://www.ncbi.nlm.nih.gov/books/NBK562933/>

Othman, Y.A., Verma, R., & Qureshi, S.A. (2019). Artificial disc replacement in spine surgery. *Annals of Translational Medicine*, 7(5) S170. doi: 10.21037/atm.2019.08.26

Schroeder, G.D., Vaccaro, A.R., Divi, S.N., Reyes, A.A., Goyal, D.K.C., Phillips, F.M., Zigler, J. (2019) *International Society for the Advancement of Spinal Surgery Position Statement on Cervical and Lumbar Disc Replacements*. <https://isass.org/position-statement-on-cervical-and-lumbar-disc-replacements-2019/>

Wang, T., Wang H., Liu, S., An, H., Liu, H., Ding, W. (2016). Anterior cervical discectomy and fusion versus anterior cervical corpectomy and fusion in multilevel cervical spondylotic myelopathy: A meta-analysis. *Medicine (Baltimore)*, 95(49). doi: 10.1097/MD.0000000000005437

This document has been classified as public information.