State of Vermont
Department of Vermont Health Access
280 State Drive, NOB 1 South
Waterbury, VT 05671-1010

Agency of Human Services
[Phone] 802-879-5903
[Fax] 802-879-5963
[Email] AHS.DVHAClinicalUnit@vermont.gov
www.dvha.vermont.gov

The Department of Vermont Health Access Clinical Criteria

Subject: Total Artificial Cervical Disc Replacement of the Spine
Last Review: August 30, 2024 *
Past Revisions: January 11, 2023

***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 pertain 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
4.106	Early and Periodic Screening, Diagnostic and Treatment (EPSDT) 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. For medical necessity clinical coverage criteria, refer to the InterQual® CP: Procedures, Artificial Disc Replacement, Cervical.
Prior Authorization is required.

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

Medicare Criteria:
- Age greater than or equal to 18 and less than or equal 60. However, there is no National Coverage Determination (NCD) for CDR, consideration will be reviewed on an individual basis.
- 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/m^2)
        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 for services performed on or after 4/27/2023.

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.

DVHA will only cover FDA approved artificial cervical disc implant devices.

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 osteophytectomy 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 osteophytectomy 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 cervical disc with synth sub, open approach
0RW30JZ	Revision of synthetic substitute in cervical disc, open approach
0RP30JZ	Removal of synth sub from cervical disc, open approach
ICD-10 Diagnosis codes CERVICAL disc	
G54.2	Cervical root disorders, not elsewhere classified
G54.9	Nerve root and plexus disorder, unspecified
M48.02	Spinal stenosis, cervical region
M50.01	Cervical disc disorder with myelopathy, high cervical region
M50.021	Cervical disc disorder at C4-C5 level with myelopathy
M50.022	Cervical disc disorder at C5-C6 level with myelopathy
M50.023	Cervical disc disorder at C6-C7 level with myelopathy
M50.11	Cervical disc disorder with radiculopathy, high cervical region
M50.121	Cervical disc disorder at C4-C5 level with radiculopathy
M50.122	Cervical disc disorder at C5-C6 level with radiculopathy
M50.123	Cervical disc disorder at C6-C7 level with radiculopathy
M50.21	Other cervical disc displacement, high cervical region
M50.221	Other cervical disc displacement at C4-C5 level
M50.222	Other cervical disc displacement at C5-C6 level
M50.223	Other cervical disc displacement at C6-C7 level
M50.31	Other cervical disc degeneration, high cervical region
M50.321	Other cervical disc degeneration at C4-C5 level
M50.322	Other cervical disc degeneration at C5-C6 level
M50.323	Other cervical disc degeneration at C6-C7 level
M53.1	Cervicobrachial syndrome

Medicare Billing and Coding Local Coverage Article A57021

Please see the Medicaid Portal at http://vtmedicaid.com/#/feeSchedule for fee schedules, code coverage, and applicable requirements.

References

Centers for Medicare & Medicaid Services. (2021, June 17). *LCD - Lumbar Artificial Disc Replacement (L37826)*. Medicare Coverage Database. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=37826&ver=21

Centers for Medicare & Medicaid Services. (2023, April 27). *LCD - Cervical Disc Replacement (L38033)*. Medicare Coverage Database. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=38033&ver=13&

Centers for Medicare and Medicaid Services. (2017). *Early and Periodic Screening, Diagnostic, and Treatment | Medicaid*. Medicaid.gov. https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html

Coric, D. (2023). Cervical arthroplasty complications and complication avoidance. *The International Journal of Spine Surgery*, *17*(6), 757–759. https://doi.org/10.14444/8537

Lee, J. H., Lee, Y. J., Chang, M. C., & Lee, J. H. (2023). Clinical effectiveness of artificial disc replacement in comparison with anterior cervical discectomy and fusion in the patients with cervical myelopathy: Systematic review and meta-analysis. *Neurospine*, *20*(3), 1047–1060. https://doi.org/10.14245/ns.2346498.249

National Institute for Health and Care Excellence (NICE). (2020). Low back pain and sciatica in over 16s: Assessment and management. In *PubMed*. National Institute for Health and Care Excellence (NICE). https://www.ncbi.nlm.nih.gov/books/NBK562933/

Phillips, F. M., Coric, D., Sasso, R., Lanman, T., Lavelle, W., Lauryssen, C., Albert, T., Cammisa, F., & Robert Alden Milam. (2023). Prospective, multicenter clinical trial comparing the M6-C compressible cervical disc with anterior cervical discectomy and fusion for the treatment of single-level degenerative cervical radiculopathy: 5-year results of an FDA investigational device exemption study. *The Spine Journal*, *24*(2), 219-230. https://doi.org/10.1016/j.spinee.2023.10.020

Schroeder, G. D., Vaccaro, A. R., Divi, S. N., Reyes, A. A., Goyal, D. K. C., Phillips, F. M., & Zigler, J. (2021). 2021 Position statement from the International Society for the Advancement of Spine Surgery on Cervical and Lumbar Disc Replacement. *International Journal of Spine Surgery*, *15*(1), 37–46. https://doi.org/10.14444/8004

This document has been classified as public information.