Artificial Disc Replacement, Cervical
Clinical Coverage Criteria

Overview

Artificial disc replacement, also known as disc arthroplasty, refers to the replacement of a symptomatic, damaged or degenerated intervertebral disc in the spine with an artificial disc. Cervical artificial disc replacement (CADR) has been proposed as an alternative to anterior cervical discectomy and fusion (ACDF) for the treatment of degenerative conditions of the cervical spine. The major potential benefits of CADR over ACDF are preservation of segmental motion and reduction in adjacent segment disease. Clinical trials, in general, have established CADR as a safe and effective alternative to ACDF in the treatment of cervical degenerative disease at 1 or 2 contiguous levels.

Policy

This Policy applies to the following Fallon Health products:

☒ Commercial
☒ Medicare Advantage
☒ MassHealth ACO
☒ NaviCare
☒ PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have a National Coverage Determination (NCD) for cervical artificial disc replacement. National Government Services, Inc. does not have a Local Coverage Determination (LCD) or Local Coverage Article (LCA) for cervical artificial disc replacement at this time (MCD search 6/15/2021).

For plan members enrolled in NaviCare, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Fallon Health's Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as authorized by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be authorized by the interdisciplinary team.

Fallon Health Clinical Coverage Criteria are used to determine medical necessity for MassHealth members. Fallon Health Clinical Coverage Criteria are developed in accordance with the definition of Medical Necessity in 130 CMR 450.204.

Prior authorization is required. The artificial disc must be approved by FDA and used in accordance with FDA-approved Labeling (Instructions for Use).

Fallon Health Clinical Coverage Criteria

Fallon Health covers cervical artificial disc replacement when all of the following criteria are met:

1. The plan member has intractable cervical radicular pain or myelopathy
    a. which has failed at least 6 weeks of conservative non-operative treatment, including active pain management program or protocol, under the direction of a physician, with pharmacotherapy that addresses neuropathic pain and other pain sources AND physical therapy; OR
    b. if the plan member has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment.
2. Degeneration is documented by magnetic resonance imaging (MRI), computed tomography (CT), or myelography.
3. Cervical degenerative disc disease is from C3-C7.

Simultaneous cervical artificial intervertebral disc implantation at a second contiguous level is covered if the above criteria are met for each disc level, and the device is FDA-approved for 2 levels (i.e., Mobi-C, Prestige LP).

Subsequent cervical artificial intervertebral disc implantation at an adjacent level is covered when all of the following are met:

1. Criteria 1 to 3 above are met; and
2. The device is FDA-approved for 2 levels; and
3. Clinical documentation that the initial cervical artificial intervertebral disc implantation is fully healed.

Revision or removal of a cervical artificial disc(s) is covered when medically necessary. Prior authorization is required.

Requests for removal of a cervical artificial disc(s) (CPT 22864 +/- 0095T) should include a request for fusion.

Exclusions

- Cervical artificial disc replacement adjacent to a previous cervical fusion is not covered.
- Cervical artificial disc replacement at three or more levels is considered experimental and is not covered.

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

Code	Description
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
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical

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Policy history

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Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.