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Medical Policy

Cervical Artificial Disc Replacement

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Product Applicability	☒ **All Plan+ Products**
Well Sense Health Plan	**Boston Medical Center HealthNet Plan**
☒ New Hampshire Medicaid	☒ MassHealth
☒ NH Health Protection Program	☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct
	☒ Senior Care Options ◊

Notes:
+ Disclaimer and audit information is located at the end of this document.
◊ The guidelines included in this Plan policy are applicable to members enrolled in Senior Care Options only if there are no criteria established for the specified service in a Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request. Review the member's product-specific benefit documents at www.SeniorsGetMore.org to determine coverage guidelines for Senior Care Options.

Policy Summary

The Plan considers the implantation of a single-level cervical artificial intervertebral disc (cervical total disc replacement/cervical artificial disc replacement) to be medically necessary for the treatment of symptomatic, single-level cervical degeneration disc disease (DDD) causing the member's intractable cervical radicular pain or myelopathy. Plan prior authorization is required. Cervical artificial disc replacement at more than one spinal level is considered experimental and investigational for any indication. Single-level cervical artificial disc replacement for the treatment of symptomatic cervical DDD at more than one level is considered experimental and investigational.

It will be determined during the Plan's prior authorization process if the service is considered medically necessary for the requested indication. See the Plan policy, *Medically Necessary* (policy number OCA 3.14), for the product-specific definitions of medically necessary treatment. Review the Plan's policy, *Experimental and Investigational Treatment* (policy number OCA 3.12), for the product-specific definitions of experimental or investigational treatment. See Plan policy*, Lumbar Artificial Disc Replacement* (policy number OCA 3.42), rather than this Policy for guidelines related to the use of artificial intervertebral lumbar discs.

Description of Item or Service

Artificial Intervertebral Disc Replacement: An artificial intervertebral disc replaces the entire disc, including nucleus, annulus, and end plate and consists of a polyurethane nucleus designed to fit between two (2) titanium alloy surfaces. An artificial disc nucleus is designed to replace only the degenerative nucleus; most of the annulus is left intact. This device consists of a hydrogel core that can absorb fluid and expand when implanted. Replacement of the intervertebral disc or the disc nucleus with an artificial device is proposed as an alternative to interbody fusion to treat symptomatic degenerative disc disease. An artificial intervertebral disc replacement is also known as an artificial disc replacement or total disc replacement.

Cervical Artificial Disc Replacement: In order to treat symptomatic cervical degeneration disc disease, a device is inserted between two (2) cervical vertebrae after an intervertebral disc has been surgically removed in the process of decompressing the spinal cord or a nerve root. The intent of the device is to preserve motion at the disc space, relieve pain, restore disc height, and prevent degeneration of adjacent discs. Cervical disc replacement surgery may be done instead of an anterior cervical discectomy and fusion (ACDF) for a patient with a cervical disc herniation between C3 to C7 with neck or arm (radicular) pain that has not responded to non-surgical treatment options and is significantly affecting the individual's quality of life and ability to function. A cervical artificial disc replacement is also known as a cervical total disc arthroplasty.

Medical Policy Statement

The Plan considers the implantation of a cervical artificial intervertebral disc (cervical total disc replacement) for the treatment of **symptomatic, single-level cervical degeneration disc disease (DDD)** to be medically necessary when ALL of the following applicable criteria are met and documented in the member's medical record, as specified below in items 1 through 8:

1. The member has intractable cervical radicular pain or myelopathy and at least ONE (1) of the following criteria is met, as specified below in item a or item b:

    a. The member has failed at least six (6) weeks of conservative, non-operative treatment under the direction of a treating physician that includes nonsteroidal anti-inflammatory drugs (NSAIDs), physical therapy, AND activity modification; OR

b. The member has severe or rapidly progressive symptoms of nerve root or spinal cord compression that requires immediate hospitalization or immediate surgical treatment; AND

2. The member's condition interferes with activities of daily living; AND

3. The member is skeletally mature and between the ages of 18 and 75 on the date of service; AND

4. Symptomatic, single-level cervical DDD is documented by magnetic resonance imaging (MRI), computed tomography (CT), or myelography with confirmation of at least ONE (1) of the following conditions as the underlying cause of the member's symptoms, as specified below in items a through c:

   a. Herniated nucleus pulposus; OR

   b. Osteophyte formation; OR

   c. Not more than 50 percent loss of disc height as compared to adjacent levels; AND

5. When there is also documented radiological evidence of asymptomatic cervical DDD at one or more spinal levels (in addition to the symptomatic, single-level cervical DDD targeted for cervical artificial disc replacement), BOTH of the following criteria must be met, as specified below in items a and b: ǂ

   a. Medical record documentation by the treating provider supports the medical necessity of the implantation of a single-level cervical artificial disc at the same level as the documented symptomatic, single-level cervical DDD; AND

   b. Medical record documentation by the treating provider states that each additional asymptomatic cervical level with DDD does not correlate with the member's clinical symptoms; AND

      ǂ Note: The Plan considers single-level cervical artificial intervertebral disc replacement to be medically necessary for documented, symptomatic cervical DDD at one level. There may ALSO be radiological evidence of asymptomatic cervical at additional spinal levels where the cervical DDD is not causing the member's symptoms of cervical radicular pain or myelopathy. Radiological evidence of DDD is common in middle aged and older individuals. Cervical artificial disc replacement at more than one spinal level is considered experimental and investigational for any indication. Single-level cervical artificial disc replacement for the treatment of symptomatic cervical DDD at more than one level is considered experimental and investigational.

6. The implant will be used in the reconstruction of a symptomatic, single-level cervical disc at C3 to C7 following a single-level discectomy at the same level; AND

7. The member does not have a previously implanted cervical artificial intervertebral disc device at another cervical level; AND

8. An FDA-approved cervical artificial intervertebral device will be used in accordance with the device's FDA labeling requirements, will be used in the reconstruction of a single-level cervical disc at C3 to C7, and will be implanted using an anterior approach.

See the Limitations section of this Plan policy for services considered experimental and investigational, contraindications to cervical artificial disc replacement, and services that require Plan Medical Director review.

Limitations

1. The removal, revision, and/or replacement of cervical artificial discs require Plan Medical Director review.

2. Plan Medical Director review is required for cervical artificial disc replacement when the member is under the age of 18 or older than age 75 on the date of service.

3. Plan Medical Director review is required for cervical artificial disc replacement for a member with documented metal hypersensitivity since this may be a risk factor for early device failure for these members. Cervical artificial disc replacement should be used with caution in patients with a documented history of an abnormal inflammatory reaction to metallic implants.

4. Cervical total disc arthroplasty (cervical artificial disc replacement) at more than one spinal level is considered experimental and investigational for any indication.

5. Hybrid surgery is considered experimental and investigational for all indications. A hybrid surgery combines cervical fusion with cervical artificial disc replacement (CADR) in a single procedure.

6. Cervical artificial disc replacement is considered experimental and investigational for a member that is not skeletally mature.

7. Contraindications for implantation of a cervical artificial disc include those on the FDA label for the specified device or at least ONE (1) of the following, as specified below in items a through f:

    a. Osteoporosis defined as dual energy X-ray absorptiometry (DEXA) bone density measured T-score of negative 2.5 or worse; OR

b. Marked cervical instability on neutral resting lateral or flexion/extension radiographs; with greater than 3 mm translation or greater than 11 degrees of angular difference to either adjacent level; OR

c. Active systemic infection or infection localized to the site of implantation; OR

d. Clinically compromised vertebral bodies at the affected level due to current or past trauma (e.g., radiographically confirmed fracture callous, vertebral crush fracture, malunion, or nonunion), anatomical deformity (e.g., rheumatoid arthritis, ankylosing spondylitis), or cervical spine malignancy; OR

e. Moderate or severe spondylosis at the level to be treated, characterized by bridging osteophytes or loss of greater than 50 percent normal disc height, or absence of motion less than 2 degrees; OR

f. Symptomatic cervical degenerative disc disease at more than one level. ǂ

ǂ Note: The Plan considers single-level cervical artificial intervertebral disc replacement to be medically necessary for documented, symptomatic cervical DDD at one level. There may ALSO be radiological evidence of asymptomatic cervical at additional spinal levels where the cervical DDD is not causing the member's symptoms of cervical radicular pain or myelopathy. Radiological evidence of DDD is common in middle aged and older individuals. Cervical artificial disc replacement at more than one spinal level is considered experimental and investigational for any indication. Single-level cervical artificial disc replacement for the treatment of symptomatic cervical DDD at more than one level is considered experimental and investigational.

8. Cervical artificial disc replacement is considered experimental and investigational for a member with ANY of the following conditions/medical history, as specified below in items a through h:

a. Prior surgery at the site with cervical degenerative disc disease (and the proposed surgical site for an artificial cervical disc); OR

b. Previous fusion at any cervical level; OR

c. Rheumatoid arthritis or other autoimmune disease; OR

d. Presence of facet arthritis; OR

e. Metabolic bone disease (e.g., Paget's disease, osteomalacia, osteoporosis, osteopenia); OR

f. Neck or arm pain of unknown etiology; OR

g. Absence of neck and/or arm pain; OR

h. Progressive neurological deficit or deterioration

Definitions

Cervical Degenerative Disc Disease (DDD): A progressive loss of disc height and instability of the cervical spinal segment(s) and associated degenerative processes, resulting in a loss of flexibility, elasticity, and shock absorbing characteristics of the cervical intervertebral disc(s). DDD involves changes in the spinal vertebrae which can destabilize the anterior spinal column and cause radiculopathy (i.e., nerve compression leading to neurological deficits and/or pain), as well as myelopathy (compression of the spinal cord). Cervical disc degeneration is a common cause of neck pain, and patients may experience additional symptoms such as numbness, tingling, and/or weakness in the neck, arms, and/or shoulders.

Cervical Myelopathy: Compression on the cervical spinal cord from either a disc herniation or cervical spinal stenosis. Symptoms include incoordination in the hands, a heavy feeling in the legs, or numbness and tingling in the legs. It is generally a slowly progressive condition and is more common in the elderly population. It is usually not painful as compression of the spinal cord does not cause pain.

Cervical Radicular Pain/Cervical Radiculopathy: The clinical description of pain and neurological symptoms resulting from any type of condition that irritates a nerve in the cervical spine. When any nerve root in the cervical spine is irritated through compression or inflammation, the symptoms can radiate along that nerve's pathway into the arm and hand. The patient's specific cervical radiculopathy symptoms will depend primarily on which nerve is affected. Cervical nerves exit the cervical spine at each level, C1 to C7. Nerves in the neck exit above the designated vertebral level at all levels except C8 which exits below the C7 vertebra. Cervical nerves branch out to supply muscles that enable the shoulders, arms, hands and fingers to function and carry sensory fibers to the skin and muscles that provide sensation.

Applicable Coding

The Plan uses and adopts up-to-date Current Procedural Terminology (CPT) codes from the American Medical Association (AMA), International Statistical Classification of Diseases and Related Health Problems, 10th revision (ICD-10) diagnosis codes developed by the World Health Organization and adapted in the United Stated by the National Center for Health Statistics (NCHS) of the Centers for Disease Control under the U.S. Department of Health and Human Services, and the Health Care Common Procedure Coding System (HCPCS) established and maintained by the Centers for Medicare & Medicaid Services (CMS). Because the AMA, NCHS, and CMS may update codes more frequently or at different intervals than Plan policy updates, the list of applicable codes included in this Plan policy is for informational purposes only, may not be all inclusive, and is subject to change without prior notification. Whether a code is listed in the Applicable Coding section of this Plan policy does not constitute or imply member coverage or provider reimbursement. Providers are responsible for

reporting all services using the most up-to-date industry-standard procedure and diagnosis codes as published by the AMA, NCHS, and CMS at the time of the service.

Providers are responsible for obtaining prior authorization for the services specified in the Medical Policy Statement section and Limitation section of this Plan policy, even if an applicable code appropriately describing the service that is the subject of this Plan policy is not included in the Applicable Coding section of this Plan policy. Coverage for services is subject to benefit eligibility under the member's benefit plan. Please refer to the member's benefits document in effect at the time of the service to determine coverage or non-coverage as it applies to an individual member. See Plan reimbursement policies for Plan billing guidelines.

CPT Codes	Description: Codes Considered Medically Necessary
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 (Note: For additional interspace cervical total disc arthroplasty, use 0092T.)
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 (Note: List separately in addition to code for primary procedure. Use 0095T in conjunction with 22864.)
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (Note: List separately in addition to code for primary procedure. Do not report 0098T in conjunction with 0095T. Use 0098T in conjunction with 22861.)

CPT Codes	Description: Codes Considered Experimental and Investigational
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)
0375T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), cervical, three or more levels

Clinical Background Information

Degenerative cervical spine disorders will affect up to two-thirds of the population in their lifetime. While often benign and episodic in nature, cervical disorders may become debilitating resulting in severe pain and other neurological symptoms. Treatment for patients who have intractable cervical disc symptoms begins with non-operative options such as medication (i.e., analgesics, anti-inflammatory drugs, and muscle relaxants), exercise, physical therapy, and immobilization. The current standard of care for patients who have intractable cervical disc symptoms that persist despite non-operative treatment is anterior cervical discectomy and fusion (ACDF), which was developed more than 50 years ago. ACDF relieves pain and other symptoms of disc degeneration by stabilizing the cervical vertebrae; to achieve this, the unhealthy disc is removed, the empty disc space is filled with a bone graft, and the graft and adjacent vertebrae are immobilized and held together with implants such as plates, screws, and cages. Although success rates can be very high (including long-term success rates), ACDF has several disadvantages that include the need for a donor bone graft site (usually the hip), bone donor site complications such as pseudarthrosis (10% to 30% rate), and loss of cervical mobility. In addition, ACDF causes biomechanical changes in the adjacent segments, including increased shear strains, higher intradiscal pressure, and increased adjacent segment motion. These changes have the potential to cause or accelerate the natural progression of DDD with an increased rate in adjacent segment disease. Artificial disc replacement (also known as total disc arthroplasty) may avoid some of these problems while providing similar clinical results.

Developers of artificial cervical discs sought to eliminate the problems associated with ACDF. Cervical artificial disc replacement was developed to relieve pain, restore disc height, maintain motion of the natural spine, and prevent potential degeneration of adjacent discs because normal anatomical alignment and motion are maintained. Cervical artificial disc replacement (also known as cervical total disc replacement or cervical disc arthroplasty) may pose less risk of DDD in adjacent cervical segments than ACDF, or delay its onset, in the adjacent cervical segments. Cervical artificial disc replacement may be performed for the same indications addressed by ACDF. However, many practitioners follow more restrictive selection criteria for total disc replacement, such as exclusion of patients with more than mild myelopathy, avoidance of surgery on C2/3 or C7/T1, and treatment of no more than one (1) or two (2) levels. In comparison to spinal fusion surgery, potential benefits of artificial disc technology may include quicker recovery time, more spine mobility after surgery, less stress on adjacent discs, and no need to harvest and use a bone graft.

Artificial disc implantation is typically performed by an orthopedic surgeon or neurosurgeon on an inpatient basis. Complications of artificial disc replacement surgery can include loosening and migration of the prosthesis (and may require emergency surgery to remove the disc), adjacent disc degeneration, polymeric and metallic wear (with load-bearing implants possibly causing wear debris over time), salvage procedures in case of failure, vascular injuries, and/or thrombolytic complications. According to the Food and Drug Administration (FDA), an artificial disc is contraindicated in individuals with spinal instability, prior major spinal surgery, spinal infection, isolated axial neck pain, ankylosing spondylitis or pregnancy, rheumatoid arthritis, autoimmune disease, diffuse idiopathic skeletal hyperostosis, severe spondylosis with bridging osteophytes or ossification of the posterior longitudinal

ligament, disc height loss greater than 50 percent, metal allergy to components of the prosthesis, severe osteoporosis/osteopenia, active malignancy, metabolic bone disease, trauma, segmental instability, three (3) or more levels requiring treatment, insulin dependent diabetes mellitus, human immunodeficiency virus, hepatitis B/C, morbid obesity, absence of motion less than two (2) degrees, and posterior facet arthrosis. Examples of cervical total disc replacement (TDR) devices approved by the FDA for single-level anterior cervical disc procedures include but are not limited to the following: the Bryan Disc (Medtronic Sofamor Danek, Memphis, TN, USA), the Prestige Disc (Medtronic Sofamor Danek, Memphis, TN, USA), and the ProDisc-C (Synthes Spine West Chester, PA, USA). Several additional cervical TDRs are currently under investigation.

At the time of the Plan's most recent policy review, no clinical guidelines were found from the Centers for Medicare & Medicaid Services (CMS) for artificial disc replacement for cervical degenerative disease. Determine if applicable CMS criteria are in effect for this service in a national coverage determination (NCD) or local coverage determination (LCD) on the date of the prior authorization request for a Senior Care Options member.

References

Ament JD, Yang Z, Nunley P, Stone MB, Kim KD. Cost-effectiveness of cervical total disc replacement vs fusion for the treatment of 2-level symptomatic degenerative disc disease. JAMA Surg. 2014. Epub ahead of print. October 8, 2014. Accessed at: http://archsurg.jamanetwork.com/article.aspx?articleid=1912412

American Academy of Orthopaedic Surgeons (AAOS). Cervical Radiculopathy: Surgical Treatment Options. June 2015. Accessed at: http://orthoinfo.aaos.org/topic.cfm?topic=A00540

American Academy of Orthopaedic Surgeons (AAOS). Neck & Back. Accessed at: http://orthoinfo.aaos.org/menus/spine.cfm

American Association of Neurological Surgeons (AANS). Patient Information. Cervical Spine. September 2007. Accessed at: http://www.aans.org/Patient%20Information/Conditions%20and%20Treatments/Artificial%20Cervical%20Disc.aspx

American College of Occupational and Environmental Medicine (ACOEM). Cervical and thoracic spine disorders. In: Hegmann KT, ed. Occupational Medicine Practice Guidelines. Evaluation and Management of Common Health Problems and Functional Recovery in Workers. 3rd ed. Elk Grove Village, IL: American College of Occupational and Environmental Medicine (ACOEM); 2011:1-332. Summary on National Guideline Clearinghouse [website]. Accessed at: http://www.guideline.gov/content.aspx?id=35207&search=cervical+disc+replacement+and+cervical+disc+arthroplasty. Accessed November 26, 2014

Anderson PA et al. Comparison of adverse events between the Bryan artificial cervical disc and anterior cervical arthrodesis. Spine. 2008 May 20;33(12):1305-12.

Braunwald, E., et al. Harrison's Principles of Internal Medicine, 15th edition; McGraw-Hill Companies, Inc., 2001. Pages 82-84.

Burkus JK, Traynelis VC, Haid RW Jr, Mummaneni PV. Clinical and radiographic analysis of an artificial cervical disc: 7-year follow-up from the Prestige prospective randomized controlled clinical trial. J Neurosurg Spine. 2014;21(4):516-528.

Centers for Medicare & Medicaid Services (CMS). Welcome to the Medicare Coverage Database. Accessed at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx

Cheng L, Nie L, Li M, Huo Y, Pan X. Superiority of the Bryan disc prosthesis for cervical myelopathy: a randomized study with 3-year followup. Clin Orthop Relat Res. 2011;469(12):3408-3414.

Coric D, Cassis J, Carew JD, et al. Prospective study of cervical arthroplasty in 98 patients involved in 1 of 3 separate investigational device exemption studies from a single investigational site with a minimum 2-year follow-up. Clinical article. J Neurosurg Spine. 2010 Dec;13(6):715-21. Accessed at: https://www.researchgate.net/publication/49649039_Coric_D_Cassis_J_Carew_JD_et_al_Prospective_study_of_cervical_arthroplasty_in_98_patients_involved_in_1_of_3_separate_investigational_device_exemption_studies_from_a_single_investigational_site_with_a

Coric D, Finger F, Boltes P. Prospective randomized controlled study of the Bryan Cervical Disc: early clinical results from a single investigational site. J Neurosurg Spine. 2006; 4(1):31-35.

Cunningham BW et al. Distribution of in vivo and in vitro range of motion following 1-level arthroplasty with the CHARITE artificial disc compared with fusion. J Neurosurg Spine. 2008 Jan;8(1):7-12.

Du J et al. Early follow-up outcomes after treatment of degenerative disc disease with the discovery of cervical disc prosthesis. Spine J. 2011 Apr;11(4):281-9. Epub 2011 Mar 5.

Garrido BJ, Taha TA, Sasso RC: clinical outcomes of Bryan cervical disc arthroplasty: a prospective, randomized, controlled, single site trial with 48-month follow-up. J Spinal Disord Tech 23: 2010.

Goffin J, Casey A, Kehr P, et al. Preliminary clinical experience with the Bryan Cervical Disc Prosthesis. Neurosurgery. 2002;51(3):840-847.

Goffin J, Geusens E, Vantomme N, et al. Long-term follow-up after interbody fusion of the cervical spine. J Spinal Disord Tech. 2004;17(2):79-85.

Goldstein JA. Artificial Disc Vs. Anterior Cervical Discectomy and Fusion. Spine Health. April 12, 2015. Accessed at: http://www.spine-health.com/treatment/artificial-disc-replacement/artificial-disc-vs-anterior-cervical-discectomy-and-fusion

Hayes Medical Technology Directory. Artificial Disc Replacement for Cervical Degenerative Disc Disease. Winifred Hayes, Inc. December 23, 2014. Reviewed December 11, 2015.

Hayes News – Government. FDA Approves Cervical Disc Device. Bryan® Cervical Disc. Winifred Hayes, Inc. May 29, 2009.

Hilibrand AS, Carlson GD, Palumbo MA, Jones PK, Bohlman HH. Radiculopathy and myelopathy at segments adjacent to the site of previous anterior cervical arthrodesis. J Bone Joint Surg Am. 1999;81(4):519-528.

Hochschuler SH. Issues to Consider Before Having Artificial Disc Surgery. Spinal Health. November 17, 2004. Accessed at: http://www.spine-health.com/treatment/artificial-disc-replacement/issues-consider-having-artificial-disc-surgery

International Society for the Advancement of Spine Surgery (ISASS). Coric D. Policy Statement - Cervical Artificial Disc. Int J Spine Surg. 2014; 8. Accessed at: http://www.isass.org/public_policy/2014-04-23-isass-policy-statement-cervical-artificial-disc.html

Jackson RJ, Davis RJ, Hoffman GA, Bae HW, Hisey MS, Kim KD, Gaede SE, Nunley PD8. Subsequent surgery rates after cervical total disc replacement using a Mobi-C Cervical Disc Prosthesis versus anterior cervical discectomy and fusion: a prospective randomized clinical trial with 5-year follow-up. J Neurosurg Spine. 2016 Jan 22:1-12. [Epub ahead of print]

Lehmann CL, Buchowski JM, Stoker GE, Riew KD. Neurologic recovery after anterior cervical discectomy and fusion. Global Spine J. 2014 Feb;4(1):41-6. doi: 10.1055/s-0033-1360723. Epub 2013 Nov 15

Lehman R, Bevenino AJ, Brewer DD, Skelly AC, and Anderson PA. A systematic review of cervical artificial disc replacement wear characteristics and durability. Evid Based Spine Care J. 2012 Feb; 3(Suppl 1): 31–38. doi: 10.1055/s-0031-1298606. PMCID: PMC3519402. Accessed at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3519402/

Lemaire JP, Clinical and Radiological Outcomes With the Charite Artificial Disc: A 10-Year Minimum Follow-Up. Journal of Spinal Disorders & Techniques. 2005 Aug; 18(4): 353-359.

LifeNet Health® Spine Bio-Implant Solutions. LifeNet Health: Extending Your Capacities in Spine Surgery. Accessed at: http://www.accesslifenethealth.org/ACCESS/uploads/files/SPINE(1).pdf

McAfee PC et al. Revisability of the CHARITE Artificial Disc Replacement: analysis of 688 patients enrolled in the U.S. IDE study of the CHARITE Artificial Disc. Spine. 2006, May 15;31(11):1217-1226.

McAnany S, Overley S, Baird E, et al. The five-year cost effectiveness of anterior cervical discectomy and fusion and cervical disc replacement: a Markov analysis. Spine (Phila Pa 1976). 2014;39(23):1924-1933.

Merrill C, Elixhauser A. Hospital Stays Involving Musculoskeletal Procedures, 1997–2005. Rockville, MD: Agency for Healthcare Research and Quality; 2007. HCUP Statistical Brief #34: Accessed at: http://www.hcup-us.ahrq.gov/reports/statbriefs/sb34.jsp

Meyler Z. What is Cervical Radiculopathy? Spine-health.™ June 10, 2011. Accessed at: http://www.spine-health.com/conditions/neck-pain/what-cervical-radiculopathy

Mikles MR and Goldstein JA. Artificial Disc for Cervical Disc Replacement. Spine-health. April 4, 2007. Accessed at: http://www.spine-health.com/treatment/artificial-disc-replacement/artificial-disc-cervical-disc-replacement

Moatz B, Tortolani PJ. Cervical disc arthroplasty: Pros and cons. Surg Neurol Int. 2012; 3(Suppl 3): S216–S224. Published online 2012 Jul 17. doi: 10.4103/2152-7806.98582. PMCID: PMC3422089. Accessed at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3422089/

Mummaneni PV, Burkus JK, Haid RW, Traynelis VC, Zdeblick TA. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. J Neurosurg Spine. 2007;6(3):198-209.

Murrey D, Janssen M, Delamarter R, et al. Results of the prospective, randomized, controlled multicenter Food and Drug Administration investigational device exemption study of the ProDisc-C total disc replacement versus anterior discectomy and fusion for the treatment of 1-level symptomatic cervical disc disease. Spine J. 2009;9(4):275-286.

Nabhan A et al. Disc Replacement using Pro-Disc C versus fusion: A prospective randomized and controlled radiographic and clinical study. Eur Spine J. 2007 March;16(3):423-430.

Nabhan a et al. The ProDisc-C prosthesis: clinical trial and radiological experience 1 year after surgery. Spine. 2007, Aug 15;32(18):1935-1941.

National Institute for Health and Clinical Excellence (NICE). Prosthetic Intervertebral Disc Replacement in the Cervical Spine. Interventional Procedure Guidance 341. May 2010. Accessed at: http://www.nice.org.uk/guidance/ipg341 or http://www.ncor.org.uk/nice-guidelines/

North American Spine Society (NASS). Baisden J. Cervical artificial disc replacement: defining appropriate coverage positions. 2014. Accessed at: https://www.spine.org/Portals/0/Documents/PolicyPractice/CoverageRecommendations/CervicalArtificialDiscReplacement.pdf.

North American Spine Society (NASS). KnowYourBack.org. Cervical Stenosis, Myelopathy and Radiculopathy. May 19, 2009. Accessed at: http://www.knowyourback.org/Pages/SpinalConditions/DegenerativeConditions/CStenosis_Myelopathy_Radiculopathy.aspx.

Peng-Fei S et al. Cervical disc prosthesis replacement and interbody fusion: a comparative study. Int Orthop. 2008 Feb;32(1):103-6.

Peng CW et al. Intermediate Results of the Prestige LP Cervical Disc Replacement: Clinical and Radiological Analysis With Minimum Two-Year Follow-up. Spine. 2011 Jan 15;36(2):E105-11.

Phillips FM, Allen TR, Regan JJ, et al. Cervical disc replacement in patients with and without previous adjacent level fusion surgery: A prospective study. Spine. 2009;34(6):556-565.

Phillips FM, Geisler FH, Gilder KM, et al. Long-term Outcomes of the US FDA IDE Prospective, Randomized Controlled Clinical Trial Comparing PCM Cervical Disc Arthroplasty With Anterior Cervical Discectomy and Fusion. Spine (Phila Pa 1976). 2015; 40(10):674-683.

Radcliff K, Lerner J, Yang C, Bernard T, Zigler JE. Seven-year cost-effectiveness of ProDisc-C total disc replacement: results from investigational device exemption and post-approval studies. J Neurosurg Spine. 2016 Jan 29:1-9. Accessed at: http://www.ncbi.nlm.nih.gov/pubmed/26824587

Radcliff K, Zigler, J, Zigler, J. Costs of Cervical Disc Replacement Versus Anterior Cervical Discectomy and Fusion for Treatment of Single-Level Cervical Disc Disease: An Analysis of the Blue Health Intelligence Database for Acute and Long-term Costs and Complications. Spine. 15 April 2015. Volume 40. Issue 8. pp. 521–529. doi: 10.1097/BRS.0000000000000822. Accessed at: http://journals.lww.com/spinejournal/Abstract/2015/04150/Costs_of_Cervical_Disc_Replacement_Versus_Anterior.8.aspx

Sasso RC et al. Artificial disc versus fusion: a prospective, randomized study with 2-year follow-up on 99 patients. Spine. 2007 Dec 15;32(26):2933-40; discussion 2941-2.

Sasso RC et al. Cervical kinematics after fusion and bryan disc arthroplasty. J Spinal Disord Tech. 2008 Feb;21(1):19-22.

Spine-health.™ Cervical Myelopathy Definition. Accessed at: http://www.spine-health.com/glossary/cervical-myelopathy

Spivak JM. Artificial Disc Replacement or Spinal Fusion: Which is Better for You? December 18, 2006. Spine-health. Accessed at: http://www.spine-health.com/treatment/back-surgery/artificial-disc-replacement-or-spinal-fusion-which-better-you

Todd AG. Cervical spine: degenerative conditions. Curr Rev Musculoskelet Med. 2011 Dec; 4(4): 168–174. Published online 2011 Sep 20. doi: 10.1007/s12178-011-9099-2. PMCID: PMC3261239. Accessed at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3261239/

Tortolani PJ et al. Prevalence of heterotopic ossification following total disc replacement. A prospective, randomized study of two hundred and seventy-six patients. J Bone Joint Surg Am. 2007 Jan;89(1):82-8.

Tracey RW, Kang DG, Cody JP, Wagner SC, Rosner MK, Lehman RA Jr. Outcomes of single-level cervical disc arthroplasty versus anterior cervical discectomy and fusion. J Clin Neurosci. 2014 Nov;21(11):1905-8. doi: 10.1016/j.jocn.2014.05.007. Epub 2014 Jun 28. Accessed at: http://www.ncbi.nlm.nih.gov/pubmed/24986154

U.S. Food and Drug Administration (FDA). BRYAN® Summary of Safety and Effectiveness Data. P060023. 2009. Accessed at: http://www.accessdata.fda.gov/cdrh_docs/pdf6/P060023a.pdf

U.S. Food and Drug Administration (FDA). Charite® Summary of Safety and Effectiveness Data. Accessed at: http://www.accessdata.fda.gov/cdrh_docs/pdf4/P040006a.pdf%20

U.S. Food and Drug Administration (FDA). Guidance for industry and Food and Drug Administration staff: Preparation and Review of investigational device exemption applications (IDEs) for total artificial discs. 2008. Accessed at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071154.htm

U.S. Food and Drug Administration (FDA). MAUDE Adverse Event Report. Manufacturer and User Facility Device Experience (MAUDE). September 30, 2014c. Accessed at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/Search.cfm

U.S. Food and Drug Administration (FDA). Mobi-C Cervical Disc Prosthesis (2-level) [labeling]. P110009. May 7, 2013b. Accessed at: http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110009c.pdf

U.S. Food and Drug Administration (FDA). Mobi-C Cervical Disc Prosthesis (single-level) [labeling]. P110002. May 7, 2013a. Accessed at: http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110002c.pdf

U.S. Food and Drug Administration (FDA). PCM Cervical Disc System. P060018. October 26, 2012. Accessed at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P100012.

U.S. Food and Drug Administration (FDA). Prestige Cervical Disc [labeling]. P060018. 2007. Accessed at: http://www.accessdata.fda.gov/cdrh_docs/pdf6/P060018c.pdf

U.S. Food and Drug Administration (FDA). PRESTIGE® LP Cervical Disc [summary of safety and effectiveness data]. P090029. July 24, 2014a. Accessed at: http://www.accessdata.fda.gov/cdrh_docs/pdf9/P090029b.pdf

U.S. Food and Drug Administration (FDA). PRESTIGE® LP Cervical Disc [labeling]. P090029. 2014b. Accessed at: http://www.accessdata.fda.gov/cdrh_docs/pdf9/P090029d.pdf

U.S. Food and Drug Administration (FDA). PRODISC®-C Summary of Safety and Effectiveness Data. Accessed at: http://www.accessdata.fda.gov/cdrh_docs/pdf7/P070001a.pdf

U.S. Food and Drug Administration (FDA). Secure-C Cervical Artificial Disc [labeling]. P100003. 2012a. Accessed at: http://www.accessdata.fda.gov/cdrh_docs/pdf10/P100003c.pdf

Wenger M, Markwalder T. Bryan total disc arthroplasty: a replacement disc for cervical disc disease. Med Devices (Auckl). 2010;3(1):11-24.

Wu AM, Xu H, Mullinix KP, Jin HM, Huang ZY, Lv QB, Wang, S, Xu HZ, Chi YL. Minimum 4-Year Outcomes of Cervical Total Disc Arthroplasty Versus Fusion. A Meta-Analysis Based on Prospective Randomized Controlled Trials. Medicine (Baltimore). 2015 Apr; 94(15): e665. Published online 2015 Apr 17. doi: 10.1097/MD.0000000000000665. PMCID: PMC4602517. Accessed at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4602517/

Yang S et al. Early and intermediate follow-up results after treatment of degenerative disc disease with the Bryan cervical disc prosthesis: single- and multiple-level. Spine. 2008 May 20;33(12):E371-7.

Young Lu, BA; McAnany SJ, Hecht AC, Cho SK, Qureshi SA. Utilization Trends of Cervical Artificial Disc Replacement After FDA Approval Compared With Anterior Cervical Fusion. Medscape. Spine. 2014;39(3):249-255. Accessed at: http://www.medscape.com/viewarticle/820057

Original Approval Date	Original Effective Date and Version Number	Policy Owner	Approved by
Regulatory Approval: N/A Internal Approval: 02/17/16: MPCTAC 03/09/16: QIC	06/01/16 Version 1	Medical Policy Manager as Chair of Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and member of Quality Improvement Committee (QIC)	Medical Policy, Criteria, and Technology Assessment Committee (MPCTAC) and Quality Improvement Committee (QIC)

Service formerly included in the *Cervical and Lumbar Artificial Disc Replacement* (policy number OCA 3.42) from 02/06/06 to 06/01/16.

Policy Revisions History			
Review Date	**Summary of Revisions**	**Revision Effective Date and Version Number**	**Approved by**
N/A	N/A	N/A	N/A

Last Review Date

02/01/16

Next Review Date

02/01/17

Authorizing Entity

QIC

Other Applicable Policies

Medical Policy - *Experimental and Investigational Treatment,* policy number OCA 3.12
Medical Policy - *Lumbar Artificial Disc Replacement,* policy number OCA 3.42
Medical Policy - *Medically Necessary,* policy number OCA 3.14

Reference to Applicable Laws and Regulations

78 FR 48164-69. Centers for Medicare & Medicaid Services (CMS). Medicare Program. Revised Process for Making National Coverage Determinations. August 7, 2013. Accessed at: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/Downloads/FR08072013.pdf

Disclaimer Information: +

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the

medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.