BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.01.108 Artificial Intervertebral Disc: Cervical Spine

Effective Policy Date: July 1, 2023

Original Policy Date: June 2012

Related Policies:

7.01.87 - Artificial Intervertebral Disc: Lumbar Spine

Artificial Intervertebral Disc: Cervical Spine

Description

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Several prosthetic devices are currently available for cervical disc arthroplasty. Cervical disc arthroplasty is proposed as an alternative to anterior cervical discectomy and fusion for patients with symptomatic cervical degenerative disc disease.

OBJECTIVE

The objective of this evidence review is to determine whether cervical disc arthroplasty improves the net health outcome compared with anterior cervical discectomy and fusion in patients who have degenerative disc disease.

POLICY STATEMENT

Cervical disc arthroplasty may be considered **medically necessary** when ALL of the following criteria are met:

1. The device is approved by the U.S. Food and Drug Administration (FDA);
2. The individual is skeletally mature;
3. The individual has intractable cervical radicular pain or myelopathy
    1. which has failed at least 6 weeks of conservative nonoperative treatment, including an 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
    2. if the individual has severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment;
4. Degeneration is documented by magnetic resonance imaging, computed tomography, or myelography;
5. Cervical degenerative disc disease is from C3 through C7; and
6. The individual is free from contraindications to cervical disc arthroplasty.

Simultaneous cervical disc arthroplasty at a second contiguous level may be considered **medically necessary** if the above criteria are met for each disc level, and the device is FDA-approved for 2 levels (eg, Mobi-C, Prestige LP™).

Subsequent cervical disc arthroplasty at an adjacent level may be considered **medically necessary** when all of the following are met:

1. Criteria 1 to 6 above are met; and
2. The device is FDA-approved for 2 levels; and
3. The planned subsequent procedure is at a different cervical level than the initial cervical artificial disc replacement; and
4. Clinical documentation that the initial cervical artificial intervertebral disc implantation is fully healed.

Cervical disc arthroplasty is considered **investigational** for all other indications, including the following:

- Disc implantation at more than 2 levels
- Combined use of an artificial cervical disc and fusion
- Prior surgery at the treated level
- Previous fusion at another cervical level
- Translational instability
- Anatomic deformity (eg, ankylosing spondylitis)
- Rheumatoid arthritis or other autoimmune disease
- Presence of facet arthritis
- Active infection
- Metabolic bone disease (eg, osteoporosis, osteopenia, osteomalacia)
- Malignancy.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

In 2007, the Prestige ST Cervical Disc (Medtronic) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process as a class III device. The Prestige ST Cervical Disc is composed of stainless steel and is indicated in skeletally mature patients for reconstruction of the disc from C3 through C7 following single-level discectomy. The device is implanted using an open anterior approach. Intractable radiculopathy and/or myelopathy should be present, with at least 1 of the following items producing symptomatic nerve root and/or spinal cord compression as documented by patient history (eg, pain [neck and/or arm pain], functional deficit, and/or neurologic deficit) and radiographic studies (eg, magnetic resonance imaging, computed tomography, x-rays): herniated disc and/or osteophyte formation.The FDA required Medtronic (the Prestige disc manufacturer) to conduct a 7-year postapproval clinical study of the safety and function of the device and a 5 year enhanced surveillance study to more fully characterize adverse events in a broader patient population.

Another disc arthroplasty product, the ProDisc-C (Synthes Spine), was approved by the FDA through the premarket approval process in 2007. As with the Prestige ST Cervical Disc, the FDA approval of ProDisc-C was made conditional on the 7 year follow-up of the 209 subjects included in the non-inferiority trial (discussed in the Rationale section), 7 year follow-up of 99 continued-access subjects, and a 5 year enhanced surveillance study to characterize more fully adverse events when the device is used under general conditions of use. The ProDisc-C Vivo is currently marketed by Centinal Spine.

More recently, continued FDA approval requires the completion of 2 postapproval studies. One study provides extended follow-up of the premarket pivotal cohort out to 7 years. The second study provides 10 year enhanced surveillance of adverse event data. Continued approval is contingent on the submission of annual reports, which include the number of devices sold, heterotopic ossification, device malfunction, device removal, other serious device-related complications, and analysis of all explanted discs.

Devices with FDA approval for use in the United States are described in Table 1. These devices are for 1 site or 2 contiguous sites, there are no devices approved for non-contiguous sites. FDA Product Code: MJO

Table 1. Cervical Disc Prostheses Approved for use in the United States

Prosthesis	Manufacturer	Characteristics	FDA Approval	Year
Prestige ST	Medtronic	Stainless steel	P060018	2007
ProDisc-C	Centinal Spine	2 metal (cobalt-chromium alloy) endplates and a polyethylene insert	P070001	2007
Bryan Cervical Disc	Medtronic Sofamor Danek	2 titanium-alloy shells encasing a polyurethane nucleus	P060023	2009
PCM [porous-coated motion] Cervical Disc	NuVasive	PCM is a semi-constrained device consisting of 2 metal (cobalt-chromium alloy) endplates and a polyethylene insert	P100012	2012
SECURE-C	Globus Medical	Semi-constrained device with 2 metal (cobalt-chromium molybdenum alloy) endplates and a polyethylene insert	P100003	2012
Mobi-C	Zimmer Biomet (previously LDR Spine)	Semi-constrained device with metal (cobalt-chromium alloy) endplates and a polyethylene insert; approved for both 1 and 2- levels	P110002/P110009	2013
Prestige LP	Medtronic Sofamor Danek	Titanium-ceramic composite with a metal-on-metal bearing; approved for both 1- and 2-levels	P090029	2014/2016
M6-C	Orthofix (previously Spinal Kinetics)	Ultra-high molecular weight polyethylene weaved fiber creating a matrix (artificial annulus) within a sheath and titanium alloy endplates	P170036	2019
Simplify Cervical Artificial Disc	NuVasive (previously Simplify Medical)	PEEK endplates and a mobile ceramic core; MRI compatible	P200022/S003	2020/2021

FDA: U.S. Food and Drug Administration; MRI: magnetic resonance imaging; PEEK: polyetheretherketone.

RATIONALE

Summary of Evidence

For individuals who have cervical radicular pain or myelopathy who receive single-level cervical disc arthroplasty, the evidence includes randomized controlled trials (RCTs) and meta-analyses of RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. At 2-year follow-up, trials of all artificial cervical discs met non-inferiority criteria compared to anterior cervical discectomy and fusion. Mid-term outcomes have been reported on 5 devices (Prestige ST, ProDisc-C, Bryan, Mobi-C, PCM [Porous Coated Motion]). At 4 to 5 years, the trial results have been consistent with the continued non-inferiority of cervical disc arthroplasty for clinical outcomes and lower cumulative reoperation rates. Seven-year follow-up of the Prestige, ProDisc-C, and Mobi-C pivotal trials continue to show lower secondary surgery rates, although this is not a consistent finding in other reports. Serious adverse events appear to be uncommon. Heterotopic ossification can occur in a substantial proportion of spinal segments with artificial intervertebral discs but does not appear to lead to a decline in clinical outcomes. The evidence to date shows outcomes that are at least as good as the standard treatment of anterior cervical discectomy and fusion. There have been no safety signals with discs approved by the U.S. Food and Drug Administration (FDA) for single-level cervical disc arthroplasty. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have cervical radicular pain or myelopathy who receive 2-level cervical disc arthroplasty of the cervical spine, the evidence includes RCTs and a non-randomized trial. Relevant outcomes are symptoms, morbid events, functional outcomes, quality of life, and treatment-related morbidity. Food and Drug Administration approval of Simplify Cervical Disc and Prestige LP for implantation at 2 levels was based on superiority to 2-level anterior cervical discectomy and fusion in overall success at 2 years. For Prestige LP, the increase in overall success rates at 2 years has been maintained for those patients who have reached the 10-year follow-up. At 2- and 4-year follow-ups, the first artificial cervical disc approved for 2 levels (Mobi-C) was found to be superior to anterior cervical discectomy and fusion for Neck Disability Index scores, Neck Disability Index success rates, reoperation rates, and the overall success composite outcome. At 5 years, trial results were consistent with the continued superiority of 2-level cervical disc arthroplasty for clinical outcomes and lower cumulative reoperation rates. Adjacent-segment degeneration with Mobi-C was found in a significantly

lower percentage of patients compared with 2-level anterior cervical discectomy and fusion patients. Based on this evidence, it can be concluded that 2-level cervical disc arthroplasty with any of these FDA-approved discs is at least as beneficial as the established alternative. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

North American Spine Society

In 2015, the guidelines from the North American Spine Society indicated that: [47,]

"Cervical artificial disc replacement, (also known as cervical total disc replacement and cervical arthroplasty) may be indicated for the following diagnoses with qualifying criteria, when appropriate:

1. Radiculopathy related to nerve root compression from one or 2 level degenerative disease (either herniated disc or spondylotic osteophyte) from C3-4 to C6-7 with or without neck pain that has been refractory to medical or nonoperative management.
2. Myelopathy or myeloradiculopathy related to central spinal stenosis from one or 2-level degenerative disc disease from C3-4 to C6-7 with or without neck pain."

International Society for the Advancement of Spine Surgery

In 2021, the International Society for the Advancement of Spine Surgery issued a position statement on cervical and lumbar disc replacement.[48,] Based on a review of the available evidence-based scientific literature, the Society "strongly supports both cervical and lumbar total disc replacements, including multi-level use as approved by the FDA, as safe and effective treatment alternatives to fusion in appropriately selected patients. FDA study guidelines and labelling regarding inclusion and exclusion criteria should be followed for use."

National Institute for Health and Care Excellence

In 2010, the National Institute for Health and Care Excellence (NICE issued guidance on the artificial cervical disc, concluding that:[49,]

"Current evidence on the efficacy of prosthetic intervertebral disc replacement in the cervical spine shows that this procedure is as least as efficacious as fusion in the short term and may result in a reduced need for revision surgery in the long term. The evidence raises no particular safety issues that are not already known in relation to fusion procedures....

This procedure should only be carried out in specialist units where surgery of the cervical spine is undertaken regularly.

NICE encourages further research into prosthetic intervertebral disc replacement in the cervical spine. Research outcomes should include long-term data on the preservation of mobility, occurrence of adjacent segment disease, and avoidance of revision surgery."

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

A search of the Medicare National Database identified a national coverage determination on artificial intervertebral discs for the lumbar spine but not for the cervical spine.[50,]

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2012	New policy	
March 2014	Replace policy	Policy updated with literature review; references 4, 7, 14-15, 24-25, 27-28, 32, 36, 44, 46-47 added and reordered; policy statement unchanged.
September 2015	Replace policy	Policy updated with literature review; references 11, 27-28, 32, 48, and 50 added; clinical input reviewed; considered medically necessary for single level cervical disc replacement.
December 2016	Replace policy	Policy updated with literature review through July 19, 2016; Rationale reorganized and references added; some references removed. Considered medically necessary for 2-level cervical disc replacement with a device that is FDA-approved for 2-levels (ie, Mobi-C, Prestige LP).
June 2018	Replace policy	Policy updated with literature review through February 5, 2018; no references added. Policy statements unchanged.
June 2019	Replace policy	Policy updated with literature review through February 5, 2019; no references added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through March 5, 2020; references added. Rationale changed to tabular format. Change in terminology from 'artificial intervertebral disc arthroplasty of the cervical spine' to 'cervical disc arthroplasty'.
June 2021	Replace policy	Policy updated with literature review through March 11, 2021; references added. Policy statements unchanged.
June 2022	Replace policy	Policy updated with literature review through March 1, 2022; reference added. Policy statements unchanged.
June 2023	Replace policy	Policy updated with literature review through March 3, 2023; references added. Minor editorial refinements to policy statements; intent unchanged.