MEDICAL POLICY

Excellus

SUBJECT: ARTIFICIAL CERVICAL INTERVERTEBRAL DISC	EFFECTIVE DATE: 03/20/08 REVISED DATE: 04/16/09, 03/18/10, 01/20/11, 01/19/12, 01/17/13, 01/16/14
POLICY NUMBER: 7.01.80 CATEGORY: Technology Assessment	PAGE: 1 OF: 8

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

Based upon our criteria and assessment of the peer-reviewed literature, artificial cervical disc replacement devices (total or partial replacement systems) are considered **investigational,** as long-term effectiveness has not been proven.

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services.

Refer to Corporate Medical Policy #7.01.63 Artificial Lumbar Intervertebral Disc.

POLICY GUIDELINES:

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

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. Interbody fusion, with or without posterior instrumentation, has been the most common surgical treatment for anterior column instability caused by degenerative disc disease. The procedure is believed to do relatively well in stabilizing the anterior column and relieving pain by eliminating motion. However, it is not physiologic and it alters the stress distribution on the adjacent segments. The issue of whether this stress alteration leads to symptomatic degeneration is still debated. It is proposed that a more functional device, an artificial disc, would restore not only the anatomy but also normal mechanical function. Many designs have been proposed over the past 40 years, both total disc and disc nucleus (partial disc replacement or PDA) devices. A total artificial disc replaces the entire disc, including nucleus, annulus, and end plate and consists of a polyurethane nucleus designed to fit between two titanium alloy surfaces. An artificial disc nucleus is designed to replace only the degenerative nucleus; most of the annulus is left intact. Partial disc replacement is also referred to as a nucleus arthroplasty.

RATIONALE:

Medtronic received FDA approval to market their Prestige® Cervical Disc System in July 2007 for skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. Evidence for the Prestige Disc is available from the non-inferiority RCT presented to the FDA comparing the Prestige disc with fusion and from a published report on 421 cases from the trial. Statistical non-inferiority was demonstrated on all outcome measures. Outcomes at two years were similar in both groups. Disc recipients improved more than the fusion group only on neurological status; however the information provided about how this was evaluated is insufficient to understand its significance. Sixty-month follow-up of participants in this clinical trial were reported by Burkus et al. All participants were followed up in this FDA-regulated post-approval study. Outcomes at 60 months were reported on approximately half of the original randomized controlled trial (RCT) participants. The majority of the remaining patients had not yet reached that point in their follow-up, rather than being lost to follow-up. About 18% of all participants were actually lost to follow-up at 60 months. The NDI improved by 38.4 points for the Prestige disc compared to 34.1 for ACDF (p=0.022). For most other clinical outcomes, the Prestige disc was similar to ACDF, with no significant difference between groups in improvement in neck pain score (56.0 vs. 52.4) or arm pain score (52.5 vs. 47.7 – both respectively). There was a trend for greater neurologic success in the Prestige disc group (95% vs. 89%, p=0.051).

Need for additional surgery was similar between the 2 procedures, and there was no significant difference in the percentage of patients requiring adjacent-level surgery (2.9% vs. 4.9% for ACDF). No implant migration was observed at up to 60 months. Bridging bone was observed in 3 of 94 patients (3.2%) with the Prestige disc.

In December 2007, the ProDisc®-C received approval from the U.S. Food and Drug Administration (FDA) based on a premarket approval application (PMA). Murrey et al. 2008 reported the 2-year follow-up of the pivotal FDA randomized non-inferiority trial to determine the safety and efficacy of ProDisc-C in comparison with anterior cervical discectomy and fusion (ACDF). Clinical outcomes at 24-months follow-up were reported to be similar in the ProDisc-C and fusion groups for the following components: neurological success (91% vs. 88%, respectively), neck disability index (21.4 vs. 20.5 points), reduction in pain scores (e.g., 46 mm vs. 43 mm reduction in neck pain on a visual analog scale), and patient satisfaction (83 mm vs. 80 mm). Four-year interim follow-up of participants in this clinical trial were reported by Delamarter et al. All participants in the clinical trial were followed up in this FDA-regulated post-approval study. At 48 months, follow-up rates for ProDisc-C and ACDF were 63% and 46.2% respectively. It was not reported what proportion of these patients had not yet reached 48 months post-surgery or were truly lost to follow-up at that time point. Also included in this report was 24-month follow-up on 77% of 136 continued access patients who received the ProDisc-C after the clinical trial. Clinical outcomes were similar between the 3 groups, with point estimates in favor of ProDisc-C. The NDI at 48 months was 20.3 for ProDisc-C versus 21.2 for ACDF. Neurologic success was achieved in 88.9% of ProDisc-C patients in comparison with 74.4% of ACDF patients (p=0.067). There was a cumulative incidence of additional surgeries of 2.9% (3 patients) in the ProDisc-C group and 11.3% (12 patients) in the ACDF group. Two patients were converted to fusion with removal of the device; one patient had decompression with supplemental fixation without removal of the device. At 48 months, 5 ProDisc-C patients (7.7%) were found to have bridging bone. Five-year results of this trial were published in 2013 with follow-up rates of 72.7% for ProDisc-C and 63.5% for ACDF by Zigler et al. and Delamarter, et al. Outcomes on the NDI were found to be similar (50-60% improved), along with VAS for arm pain (18 for both groups) and scores on the SF-36. VAS for neck pain was modestly improved with ProDisc-C compared to ACDF (21 vs. 30), although the proportion of patients who achieved a clinically significant improvement in neck pain was not reported. There was a lower percentage of patients with ProDisc-C who had secondary surgery at either the index or adjacent level (2.9% vs. 14.5%).

The Bryan® Cervical Disc System received FDA approval based on PMA clearance in May 2009. Based on the information provided from the manufacturer and the FDA premarket approval, the device is indicated in skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The BRYAN® device is implanted via an open anterior approach. Patients receiving the BRYAN® Cervical Disc should have failed at least six weeks of non-operative treatment prior to implantation of the device. Heller and colleagues published the results of a non-inferiority trial in 2009. This multicenter RCT investigated the safety and efficacy of the device in 242 patients compared to 221 patients undergoing an anterior cervical discectomy. At 24-month follow-up both groups had similar improvements in clinical outcomes. Four-year follow-up from the IDE trial was reported for 181 patients (75% of 242) who received the Bryan disc and 138 patients (62% of 223) who underwent ACDF. (Sasso, et al.) It was reported that 25% of AIDA and 38% of the ACDF patients failed to return for follow-up at 48 months, due in part to FDA and institutional review board approvals and the need for additional patient consent for the continuation study. Overall success was defined as an improvement of equal to or greater than 15 points in the NDI, neurologic improvement, no serious adverse events related to the implant or surgical implantation procedure, and no subsequent surgery or intervention that would be classified as a treatment failure. The 4-year overall success rates were significantly greater in the Bryan (85.1%) than the ACDF (72.5%) group. This finding was driven largely by differences in the NDI success (90.6% of arthroplasty and 79.0% of ACDF). Neurologic success rates were not different between the groups. Arm pain improved from a baseline of 71.2 in both groups to 16.6 for the Bryan disc and 22.4 for ACDF, the difference between groups was statistically significant. The improvement in neck pain scores was also significantly better in the Bryan disc group (from 75.4 to 20.7) compared to patients with fusion (from 74.8 to 30.6). Improvement in the SF-36 physical component score was also significantly greater in the arthroplasty group (15.8 vs. 13.1). There was no significant difference in additional surgical procedures at either the index (3.7% Bryan, 4.5% ACDF) or adjacent (4.1% Bryan, 4.1% ACDF) levels. FDA-required follow-up will continue for 10 years after the index surgery.

The PCM [porous coated motion] Cervical Disc® (NuVasive), which received 5-year FDA approval in October 2012, is a semi-constrained device consisting of two metal (cobalt-chrome alloy) endplates and a polyethylene insert that fits between the endplates. Continued approval is contingent on the submission of annual reports, which should include the number of devices sold, analysis of all explanted discs, and 7-year follow-up of the pre-market cohort with an evaluation of overall success. In addition, NuVasive will conduct 10-year enhanced surveillance of device-related adverse events. Results of the 2-year FDA-regulated multicenter randomized non-inferiority trial of the PCM Cervical Disc were reported by Phillips and colleagues in 2013. The investigator and surgical staff were not blinded to treatment assignment, and patients were informed of the treatment assignment after surgery. Out of the 416 patients who were randomized (224 PCM, 192 ACDF), 340 (82%, 189 PCM and 151 ACDF) were per protocol for the 24-month primary endpoint of overall success. Overall success was defined as at least 20% improvement in NDI; absence of reoperation, revision, or removal; maintenance or improvement in neurological status; and absence of radiographic or major complications during the 24-month follow-up period. At 24 months, overall success was 75.1% in the PCM group and 64.9% in the ACDF group, which was statistically non-inferior and superior for AIDA. There was a trend toward a greater neurological success rate in the PCM group (94.7%) compared with ACDF (89.5%, $p = 0.10$). There was no significant difference between the groups for VAS pain scores, SF-36 component scores, or implant- or surgery-related adverse events (5.2% PCM vs. 5.4% ACDF). Patients with prior fusion were included in this study. Overall success for the 2 sub-groups in this analysis was similar (65.4% PCM and 64.3% ACDF).

On September 28, 2012, the FDA approved the SECURE-C Artificial Cervical Disc, which is intended to be used in skeletally mature patients to replace a cervical disc (from C3 to C7) following removal of the disc for conditions that result from a diseased or bulging disc (intractable radiculopathy or myelopathy) at only 1 level. The approval was based on a prospective, multi-center, two-arm, randomized (1:1), unmasked, concurrently controlled, non-inferiority clinical study that compared the safety and effectiveness of the SECURE®-C Cervical Artificial Disc to the standard of care, anterior cervical discectomy and fusion (ACDF) using a plate (ASSURE® Anterior Cervical Plate System) and structural allograft in treating patients with intractable symptomatic cervical disc disease (SCDD) at one level between C3 and C7. Based on the FDA conclusion, the study data indicated that, at 24 months postoperatively, the SECURE®-C device is at least as effective as the ACDF control group in terms of clinically significant improvement on the Neck Disability Index and maintenance or improvement in neurological status and is statistically superior to the ACDF control group in terms of subsequent surgeries at the index level, device-related adverse event rates, and overall success according to both composite definitions analyzed.

The Mobi-C® Cervical Disc Prosthesis received FDA approval August 2013. It is indicated in skeletally mature patients for reconstruction of the disc at either one or two levels level from C3-C7 following discectomy for intractable radiculopathy (arm pain and/or a neurological deficit) with or without neck pain, or myelopathy due to diseased discs at one level or two adjacent levels. The Mobi-C® Cervical Disc Prosthesis is implanted using an anterior approach. Patients should have failed at least 6 weeks of conservative treatment or demonstrated progressive signs or symptoms despite nonoperative treatment prior to implantation of the Mobi-C® Cervical Disc Prosthesis. Data from a single level clinical study was the basis for the PMA approval decision. The study was a prospective, multi-center, two-arm, randomized (2:1), unmasked, concurrently controlled, non-inferiority clinical study to compare the safety and effectiveness of the Mobi-C® Cervical Disc Prosthesis to the standard of care, anterior cervical discectomy and fusion (ACDF). The study data indicated that, at 24 months postoperatively, the Mobi-C® device is at least as effective as the control treatment (ACDF), for the patient population and indications studied in this investigation, in terms of the overall success according to the protocol-specified composite primary endpoint and alternative primary endpoint definitions analyzed.

Several other devices are under study in FDA Investigational Device Exemption (IDE) trials in the U.S., but final approval of those is not expected for several years. These include: Cervicore, Flexicore, Kineflex C, Discover, and NeoDisc.

In summary, evidence to date has not shown a beneficial effect of any cervical disc product on the development of adjacent level disease, whereas long-term complication rates with artificial discs remain unknown. Further, given the clinical situation, follow-up thus far is not adequate to evaluate long-term results, in particular any effect of the device on

adjacent-level disc degeneration, device durability, adverse events, and revisability. Finally, because the performance of each disc type may vary, each disc design will require its own long-term studies to evaluate device-specific performance.

Partial disc replacement systems are in the earliest stages of investigation. Partial disc replacement systems are considered investigational due to the lack of FDA approval and lack of long-term studies of these devices that demonstrate their safety and improvement on patient health outcomes over standard fusion procedures.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT:

22856	**(E/I)**	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
0092T	**(E/I)**	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), each additional interspace, cervical
22861	**(E/I)**	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace, cervical
0098T	**(E/I)**	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical
22864	**(E/I)**	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace, cervical
0095T	**(E/I)**	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical

HCPCS: No codes

ICD9: Investigational for all codes

ICD10: Investigational for all codes

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* key article

KEY WORDS:

Artificial Disc, Bryan, Mobi-C, PCM [porous coated motion] Cervical Disc® Prestige, ProDisc, SECURE-C

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, artificial cervical intervertebral disc is not addressed in National or Regional Medicare coverage determinations or policies.