



MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 10/11/16
LAST REVIEW DATE: 06/05/18
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

ARTIFICIAL INTERVERTEBRAL DISC OF THE CERVICAL SPINE

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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ARTIFICIAL INTERVERTEBRAL DISC OF THE CERVICAL SPINE (cont.)

Description:

Artificial intervertebral disc arthroplasty (AIDA) of the cervical spine is proposed as an alternative to anterior cervical discectomy and fusion (ACDF) for individuals with symptomatic cervical degenerative disc disease (DDD).

Artificial cervical disc devices with FDA approval for single level disc replacement:

- Bryan® Cervical Disc
- Mobi-C®
- PCM® (porous coated motion) Cervical Disc
- Prestige® LP
- Prestige® ST Cervical Disc
- ProDisc®-C
- Secure®-C

Artificial cervical disc devices with FDA approval for two level disc replacement:

- Mobi-C
- Prestige LP

Artificial disc devices currently under investigation include, *but are not limited to*:

- CerviCore™ Intervertebral Disc
- Discover® Artificial Cervical Disc
- Freedom® Cervical Disc
- Kineflex®-C Cervical Artificial Disc Implant
- M6®-C Artificial Cervical Disc
- NeoDisc™ Artificial Cervical Disc

Disc nucleus replacement devices, also known as prosthetic disc nucleus (PDN) devices, have also been investigated for the treatment of degenerative disc disease.

ARTIFICIAL INTERVERTEBRAL DISC OF THE CERVICAL SPINE (cont.)

Criteria:

- Cervical artificial intervertebral disc implantation¹ at a single level is considered **medically necessary** with documentation of **ALL** of the following:
 1. Device is approved by FDA
 2. Individual is skeletally mature (radiographic evidence of epiphyseal closure)
 3. Individual has intractable cervical radicular pain or myelopathy with documentation of **ANY** of the following:
 - Failed at least 6 weeks of conservative nonoperative 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
 - 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 (MRI), computed tomography (CT), or myelography
 5. Cervical degenerative disc disease is from C3-C7
 6. Free from contraindication to cervical artificial intervertebral disc implantation¹
- Simultaneous cervical artificial intervertebral disc implantation¹ at a second contiguous level is considered **medically necessary** with documentation of **ALL** of the following:
 1. Criteria for single level are met for each disc level
 2. Device is approved by FDA for two levels
- Subsequent cervical artificial intervertebral disc implantation¹ at an adjacent level is considered **medically necessary** with documentation of **ALL** of the following:
 1. Criteria for single level are met for each disc level
 2. Device is approved by FDA for two levels
 3. The planned subsequent procedure is at a different cervical level than the initial cervical artificial disc replacement
 4. Clinical documentation that the initial cervical artificial intervertebral disc implantation is fully healed

ARTIFICIAL INTERVERTEBRAL DISC OF THE CERVICAL SPINE (cont.)

Criteria: (cont.)

- Cervical artificial intervertebral disc implantation¹ for all other indications not previously listed or if above criteria is not met is considered **experimental or investigational** based upon:
1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

These indications include, *but are not limited to*:

- Disc implantation at more than two levels
 - Combined use of an artificial cervical disc and fusion
 - Prior surgery at the treated level
 - Previous fusion at another cervical level
 - Translational instability
 - Anatomical deformity (e.g., ankylosing spondylitis)
 - Rheumatoid arthritis or other autoimmune disease
 - Presence of facet arthritis
 - Active infection
 - Metabolic bone disease (e.g., osteoporosis, osteopenia, osteomalacia)
 - Malignancy
- Disc nucleus replacement is considered **experimental or investigational** based upon:
1. Lack of final approval from the Food and Drug Administration, and
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 3. Insufficient evidence to support improvement of the net health outcome, and
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 5. Insufficient evidence to support improvement outside the investigational setting.

¹ Artificial disc replacement does *not* include fusion cage, dowel or support structure.



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Resources:

Literature reviewed 06/05/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 10/29/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 7.01.108 BCBS Association Medical Policy Reference Manual. Artificial Intervertebral Disc: Cervical Spine. Re-issue date 04/12/2018, issue date 10/10/2006.
2. Hisey MS, Bae HW, Davis RJ, et al. Prospective, Randomized Comparison of Cervical Total Disk Replacement Versus Anterior Cervical Fusion: Results at 48 Months Follow-up. *J Spinal Disord Tech.* May 2015;28(4):E237-243.
3. Murtagh R, Castellvi AE. Motion preservation surgery in the spine. *Neuroimaging Clin N Am.* May 2014;24(2):287-294.
4. Zhang Y, Liang C, Tao Y, et al. Cervical total disc replacement is superior to anterior cervical decompression and fusion: a meta-analysis of prospective randomized controlled trials. *PloS one.* 2015;10(3):e0117826.



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíílkidgo beehaz'ánii hólo díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilínígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.

