

Department of Origin: Integrated Healthcare Services	Effective Date: 09/10/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 09/10/24
Clinical Policy Document: Intervertebral Disc Prosthesis, Cervical and Lumbar	Replaces Effective Clinical Policy Dated: 09/28/23
Reference #: MC/F022	Page: 1 of 6

PURPOSE:

The intent of this clinical policy is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:

Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost-effective alternative must be requested for coverage consideration.

GUIDELINES:

Medical Necessity – Must satisfy the following: I - II, and not III

- I. Cervical Spine – Requests for intervertebral disc prosthesis at 1 or 2 contiguous levels from C3-C7 – must satisfy all of the following: A – D, and not E
 - A. The member is skeletally mature; and
 - B. The member has *cervical radiculopathy* or *myelopathy* which has failed at least 6 weeks of conservative treatment within 1 year prior to the scheduled surgery date. The conservative treatment must have included physical therapy, unless there is evidence of a neurosurgical emergency, such as, but not limited to *cord compression*; and
 - C. Findings on imaging, based on an official radiology report, show any of the following: 1 - 4
 1. Herniated disc; or
 2. Osteophytes (bone spurs); or
 3. Loss of disc height; or
 4. Foraminal stenosis.
 - D. Recent imaging has reasonably excluded alternate causes of pain.
 - E. Intervertebral disc prosthesis (artificial disc replacement) at one or more level(s) combined with spinal fusion (arthrodesis) at another level (adjacent or non-adjacent) (also known as a *hybrid procedure*) is investigative (see Investigative List).
- II. Lumbar Spine – Requests for single-level intervertebral disc prosthesis – must satisfy all of the following: A – E, and not F
 - A. The member is skeletally mature; and
 - B. The member has low back pain which has failed at least 6 months of conservative treatment within 1 year prior to the scheduled surgery date. The conservative treatment must have included

Department of Origin: Integrated Healthcare Services	Effective Date: 09/10/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 09/10/24
Clinical Policy Document: Intervertebral Disc Prosthesis, Cervical and Lumbar	Replaces Effective Clinical Policy Dated: 09/28/23
Reference #: MC/F022	Page: 2 of 6

physical therapy, unless there is evidence of *cord compression*; and

- C. Findings on imaging show either 3mm or less of *spondylolisthesis* or no more than Grade I *spondylolisthesis* localized to the disc space being treated; and
- D. Recent imaging has reasonably excluded alternate causes of pain; and
- E. The targeted surgical level has been determined to be the member's primary pain generator per localizing symptoms, localizing signs, imaging or ancillary studies (eg, discogram).
- F. Intervertebral disc prosthesis (artificial disc replacement) at one or more level(s) combined with spinal fusion (arthrodesis) at another level (adjacent or non-adjacent) (also known as a *hybrid procedure*) is investigative (see Investigative List).

III. Use of intervertebral disc prostheses are not indicated for any of the following: A - B

- A. Placement of prosthetic intervertebral discs for persons who have symptomatic degenerative disc disease or signs and symptoms of herniated disc beyond the proposed surgical site.
- B. Placement of a prosthetic intervertebral disc that would result in more than 2 contiguous cervical artificial discs.

EXCLUSIONS (not limited to):

Refer to member's Certificate of Coverage or Summary Plan Description

The following are considered investigative (see Investigative List): I - III

- I. Intervertebral thoracic disc prosthesis
- II. Intervertebral lumbar disc prosthesis at more than one level
- III. Intervertebral disc prosthesis (artificial disc replacement) at one or more level(s) combined with spinal fusion (arthrodesis) at another level (adjacent or non-adjacent) (also known as a *hybrid procedure*)

DEFINITIONS:

Cervical Radiculopathy:

Disease marked by cervical nerve root compression/impingement due to herniated disc material, osteophytes (bone spurs), cervical spondylosis, and others. This typically produces neck and radiating arm pain or numbness in the pathway of a specific nerve root, sensory deficits, or motor dysfunction in the neck and upper extremities.

Cord Compression/Thecal Sac Compression:

Radiologic evidence of indentation of the thecal sac or spinal cord compression, whether or not there are neurologic signs and symptoms associated with compression.

Hybrid procedure:

Intervertebral disc prosthesis (artificial disc replacement) at one or more level(s) level combined with spinal fusion surgery at another level (adjacent or non-adjacent).

Department of Origin: Integrated Healthcare Services	Effective Date: 09/10/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 09/10/24
Clinical Policy Document: Intervertebral Disc Prosthesis, Cervical and Lumbar	Replaces Effective Clinical Policy Dated: 09/28/23
Reference #: MC/F022	Page: 3 of 6

Myelopathy:

Any neurologic deficit related to the compression of the spinal cord, usually due to osteophytes (bone spurs) or disc herniation, sometimes also caused by trauma, carcinoma metastatic to bone, cysts, and benign neoplasms.

Spinal Instability:

According to the American Academy of Orthopaedic Surgeons, instability is defined as an abnormal response to applied loads, characterized by movement in the motion segment beyond normal constraints. A motion segment is the smallest functional spinal unit exhibiting the generic biomechanical characteristics of the spine. It consists of two adjacent vertebrae, an intervertebral disc, various ligaments and apophyseal joints. Stability to the motion segment is provided by the ligaments, facet joints and intervertebral discs which restrict its range of movements.

Spondylolisthesis:

A condition in which a vertebra usually located in the lower region of the spine slips from its original position and slides forward over the vertebra located below it.

Spondylolisthesis Grades:

Grade I	25% of vertebral body has slipped forward
Grade II	50%
Grade III	75%
Grade IV	100%
Grade V	Vertebral body completely fallen off (ie, spondyloptosis)

Spondylolysis:

A defect in the pars interarticularis of the neural arch, that portion of the neural arch that connects the superior and inferior articular facets.

BACKGROUND:

Intervertebral disc prosthesis is also known as total disc replacement (TDR), artificial disc replacement, and total disc arthroplasty.

The intervertebral disc prosthesis must be FDA-approved for both the condition and the number of levels being treated.

Examples of FDA-approved cervical prosthetic intervertebral discs include the Bryan® Cervical Disc, M6-C™ Artificial Cervical Disc, Mobi-C® Cervical Disc Prosthesis, PCM® Cervical Disc System, Prestige® Cervical Disc System, ProDisc™ - C Total Disc Replacement, SECURE®-C Cervical Artificial Disc, Simplify® Cervical Artificial Disc, and Prestige® LP cervical artificial intervertebral disc.

Examples of FDA-approved lumbar prosthetic intervertebral discs include the activL® Artificial Disc, the Charite® / INMOTION® Artificial Disc, and the ProDisc®-L Total Disc Replacement. Currently, there are no FDA-approved thoracic intervertebral disc prosthetic devices.

Department of Origin: Integrated Healthcare Services	Effective Date: 09/10/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 09/10/24
Clinical Policy Document: Intervertebral Disc Prosthesis, Cervical and Lumbar	Replaces Effective Clinical Policy Dated: 09/28/23
Reference #: MC/F022	Page: 4 of 6

Prior Authorization: Yes, per network provider agreement.
Precertification: Yes

CODING:

CPT® or HCPCS

- 22856 Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical
- 22857 Insertion of artificial disc between bones of lower spine, single space
- 22858 Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophyctomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure)

CPT codes copyright 2024 American Medical Association. All Rights Reserved. CPT is a trademark of the AMA. The AMA assumes no liability for the data contained herein.

REFERENCES:

1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: Coverage Determination Guidelines (MP/C009)
3. American Association of Neurological Surgeons (AANS). Artificial Disc Replacement Health Center [website]. <https://www.spine-health.com/treatment/artificial-disc-replacement>.
4. Seidenwurm DJ. Myelopathy. *American Journal of Neuroradiology*. 2008;29(5):1032-1034. Retrieved from <http://www.ajnr.org/content/29/5/1032>.

Cervical Intervertebral Disc Prosthesis

1. American Association of Neurological Surgeons (AANS). Artificial Cervical Disc Surgery. 2024. <https://www.aans.org/patients/conditions-treatments/artificial-cervical-disc-surgery/>. Accessed 06-26-24.
2. Goldstein JA. Considerations for Cervical Disc Replacement Surgery. 2019. Retrieved from <https://www.spine-health.com/treatment/artificial-disc-replacement/indications-artificial-cervical-disc>. Accessed 06-26-24.
3. Eubanks JD. Cervical radiculopathy: nonoperative management of neck pain and radicular symptoms. *American Family Physician*. 2010;81(1). Retrieved from <https://www.aafp.org/pubs/afp/issues/2010/0101/p33.html>. Accessed 06-26-24.
4. Hu Y, Guohua L, Ren S, Johansen D. Mid- to long-term outcomes of cervical disc arthroplasty versus anterior cervical discectomy and fusion for treatment of symptomatic cervical disc disease: a systematic review and meta-analysis of eight prospective randomized controlled trials. *PLoS ONE*, 2016;11(2). doi: 10.1371/journal.pone.0149312.
5. Sinicropi SM. Two-Level Cervical Disc Replacement. 2015. Retrieved from <https://www.spine-health.com/treatment/artificial-disc-replacement/two-level-cervical-disc-replacement>. Accessed 06-26-24.
6. FDA. Summary of Safety and Effectiveness Data (SSED). M6-C™ Artificial Cervical Disc. 2019. Retrieved from https://www.accessdata.fda.gov/cdrh_docs/pdf17/P170036B.pdf. Accessed 06-26-24.
7. FDA. Summary of Safety and Effectiveness Data (SSED). Simplify® Cervical Artificial Disc. 2021. Retrieved from https://www.accessdata.fda.gov/cdrh_docs/pdf20/P200022B.pdf. Accessed 06-26-24.
8. Fernandes A, Joaquim OTdS, Rhee J, Riew KD. In: Joaquim AF, et al, eds. Degenerative

Department of Origin: Integrated Healthcare Services	Effective Date: 09/10/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 09/10/24
Clinical Policy Document: Intervertebral Disc Prosthesis, Cervical and Lumbar	Replaces Effective Clinical Policy Dated: 09/28/23
Reference #: MC/F022	Page: 5 of 6

Cervical Spine Disease. *Fundamentals of Neurosurgery. A Guide for Clinicians and Medical Students*: Springer Nature Switzerland AG 2019, p. 228.

9. Kotharj MJ, Chuang K. Treatment and prognosis of cervical radiculopathy. (Topic 5263, Version 32.0; last updated 02/28/23). In: Goddeau RP Jr., ed. *UpToDate*. Waltham, Mass.: UpToDate; 2023. www.uptodate.com. Accessed 06-26-24.

Lumbar Intervertebral Disc Prosthesis

1. American Association of Neurological Surgeons (AANS). Artificial Lumbar Disc Surgery. Retrieved from <https://www.aans.org/patients/conditions-treatments/artificial-lumbar-disc-surgery/>. Accessed 06-26-24.
2. Formica M, Divano S, Cavagnaro L, et al. Lumbar total disc arthroplasty: outdated surgery or here to stay procedure? A systematic review of current literature. *J Orthop Traumatol*. 2017 Sep;18(3):197-215.
3. Garcia R Jr, Yue JJ, Blumenthal S, et al. Lumbar Total Disc Replacement for Discogenic Low Back Pain: Two-year Outcomes of the activL Multicenter Randomized Controlled IDE Clinical Trial. *Spine (Phila Pa 1976)*. 2015;40(24):1873-81.
4. Nie H, Chen G, Wang X, Zeng J. Comparison of Total Disc Replacement with lumbar fusion: a meta-analysis of randomized controlled trials [abstract]. *J Coll Physicians Surg Pak*. 2015 Jan;25(1):60-7.
5. Zigler J. Total Disc Replacement-Lumbar Artificial Disc Replacement. 2018. Retrieved from <https://www.spine-health.com/treatment/artificial-disc-replacement/total-disc-replacement-lumbar-artificial-disc-replacement>. Accessed 06-26-24.
6. Zigler J, Ferko N, Cameron C, Patel L. Comparison of therapies in lumbar degenerative disc disease: a network meta-analysis of randomized controlled trials. *J Comp Eff Res*. 2018 Mar;7(3):233-246.
7. Zigler J, Gornet MF, Ferko N, Cameron C, Schranck FW, Patel L. Comparison of lumbar total disc replacement with surgical spinal fusion for the treatment of single-level degenerative disc disease: a meta-analysis of 5-year outcomes from randomized controlled trials. *Global Spine Journal*. 2017.
8. Chou R. Subacute and chronic low back pain: Surgical treatment. (Topic 4469, Version 46.0; last updated 09/27/23). In: Law K, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2023. www.uptodate.com. Accessed 06-26-24.

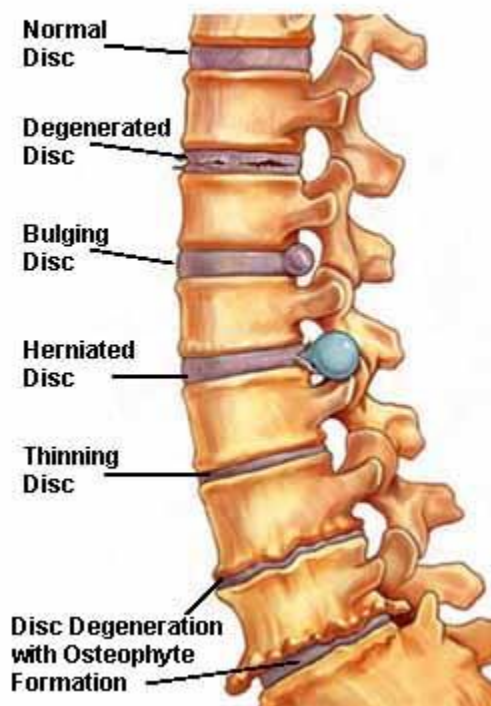
DOCUMENT HISTORY:

Created Date: 09/23/08
Reviewed Date: 08/26/09, 08/03/10, 07/21/11, 07/17/12, 07/17/13, 05/31/19, 05/29/20, 05/28/21, 05/23/22, 05/23/23, 05/20/24
Revised Date: 07/17/12, 07/26/19, 06/28/20, 06/11/11, 06/14/21, 05/27/22, 05/31/22, 02/09/23, 04/11/23, 06/01/23
Retired Date: 08/08/14 Re-adopted: 05/31/18

Department of Origin: Integrated Healthcare Services	Effective Date: 09/10/24
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 09/10/24
Clinical Policy Document: Intervertebral Disc Prosthesis, Cervical and Lumbar	Replaces Effective Clinical Policy Dated: 09/28/23
Reference #: MC/F022	Page: 6 of 6

Attachment A

Examples of Disc Problems



Source: Spineuniverse; Intervertebral Disc Replacement A Role in the Management of Chronic Low Back Pain Caused by Degenerative Disc Disease <https://www.spineuniverse.com/treatments/emerging/artificial-discs/intervertebral-disc-replacement>

Nondiscrimination & Language Access Policy



Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:

Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If you need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If you believe that Aspirus Health Plan, Inc. 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:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If you need help filing a *grievance*, the Nondiscrimination Grievance 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, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitmi shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë. Telefononi në 1-800-332-6501 (TTY: 711).

Arabic: تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف 1-800-332-6501 (رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: या नद : य द आप िहंदी बोलते ह तो आपके िलए मु त म भाषा सहायता सेवाएं उपल थ ह 1-800-332-6501 (TTY: 711) पर कॉल कर ।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-800-332-6501 (TTY: 711) 번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzsch, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ ໂດຍບໍ່ເສັຽຄ່າ, ຈະມີມື້ອມໃຫ້ທ່ານ. ໂທສ 1-800-332-6501 (TTY: 711).