

Department of Origin: Integrated Healthcare Services	Effective Date: 09/28/23
Approved by: Medical Policy Quality Management Subcommittee	Date Approved: 09/22/23
Clinical Policy Document: Intervertebral Disc Prosthesis, Cervical and Lumbar	Replaces Effective Clinical Policy Dated: 04/19/23
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

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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).

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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.

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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)

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Cervical Intervertebral Disc Prosthesis

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Lumbar Intervertebral Disc Prosthesis

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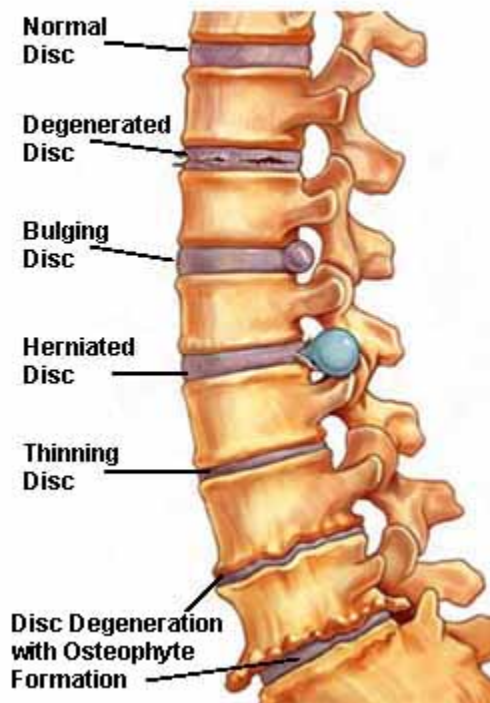
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Attachment A

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>

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PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist 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>.

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200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

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ဟံသာဝတီ: နမူနာတို့ ကညီ ကျိအသိ, နမူနာ ကျိအတိအကျတို့ တလက်ကွက်လက်စွာ နှိတ်ခံဘက်သို့လွှဲလိ။ ကိ: 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន: បើសិនជាអ្នកនិយាយភាសាខ្មែរ, សេវាជំនួយភាសា ដោយមិនគិតថ្លៃ គឺអាចមានសំរាប់អ្នក។ ហៅ 1.800.940.5049 (TTY: 763.847.4013).

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).