

Artificial Intervertebral Discs

Last Review Date: November 10, 2023

Number: MG.MM.SU.46fC2

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Definitions

Artificial discs	Devices constructed from metal, plastic, titanium or polyurethane, which are surgically implanted between the spinal vertebrae as a replacement for diseased/damaged discs to provide relief for intractable pain.										
Cervical degenerative disc disease (CDD)	Defined as neck or arm (radicular) pain and/or a functional/neurological deficit with at least one of the following conditions confirmed by imaging (CT, MRI, or X-rays): <ol style="list-style-type: none"> 1. Herniated nucleus pulposus 2. Spondylosis (defined by the presence of osteophytes) 3. Loss of disc height. 										
Degenerative disc disease (DDD)	Defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies.										
Intractable radiculopathy/or myelopathy	Defined as any combination of the following: <ol style="list-style-type: none"> 1. Disc herniation with radiculopathy 2. Spondylotic radiculopathy 3. Disc herniation with myelopathy 4. Spondylotic myelopathy resulting in impaired function and at least one clinical neurological sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using computed tomography (CT), myelography and CT, and/or magnetic resonance imaging (MRI). 										
Spondylolisthesis	Defined as anterior or posterior displacement (slippage) of a vertebra or the vertebral column in relation to the vertebrae below; described by millimeters or grading per the table following table. <table border="1" data-bbox="391 1734 1511 1923"> <tr> <td>Grade 1</td> <td>0–25% of vertebral body has slipped forward</td> </tr> <tr> <td>Grade 2</td> <td>25–50%</td> </tr> <tr> <td>Grade 3</td> <td>50–75%</td> </tr> <tr> <td>Grade 4</td> <td>75–100%</td> </tr> <tr> <td>Grade 5</td> <td>> 100% = vertebral body completely fallen off (i.e., spondyloptosis)</td> </tr> </table>	Grade 1	0–25% of vertebral body has slipped forward	Grade 2	25–50%	Grade 3	50–75%	Grade 4	75–100%	Grade 5	> 100% = vertebral body completely fallen off (i.e., spondyloptosis)
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Guideline

Artificial discs are FDA-approved for use in skeletally mature individuals per the table below.
(List not intended as all-inclusive)

	Device	Indication
Cervical	BRYAN® Cervical Disc	Radiculopathy/myelopathy (C3–C7) (single level)
	M6-C™ Artificial Cervical Disc	Radiculopathy/myelopathy (C3–C7) (single level)
	Mobi-C® Cervical Disc Prosthesis	Radiculopathy/myelopathy (C3–C7) (two level)
	PCM Cervical Disc System	Radiculopathy/myelopathy (C3–C7) (single level)
	Prestige® Cervical Disc System	Radiculopathy/myelopathy (C3–C7) (single level)
	Prestige LP Cervical Disc	Radiculopathy/myelopathy (C3–C7) (single level)
	ProDisc™-C Total Disc Replacement	CDD (C3–C7) (single level)
	SECURE®-C Artificial Cervical Disc	Radiculopathy/myelopathy (C3–C7) (single level)
	Lumbar	activL® Artificial Disc
CHARITÉ™ Artificial Disc		DDD (L4–S1): No > 3mm of spondylolisthesis at the involved level (single level)
PRODISC®-L Total Disc Replacement		DDD (L3–S1): No > Grade 1 spondylolisthesis at involved level (single level)

Members with single-level lumbar disc disease (or 1–2 contiguous cervical-level disease) are eligible for coverage of artificial prosthetic disc replacement with an FDA-approved device when the following criteria are met:

1. Skeletal maturity
2. Disease confirmed by radiological imaging (e.g., CT or MRI scan followed by discogram*)
3. Pain confined to operative level(s) (by discogram)
4. Pain score ≥ 40 on Visual Analog Scale (VAS)
5. Disability score ≥ 30 on Oswestry Low Back Pain Disability Questionnaire or Neck Disability Index
6. Failure of ≥ 6 months consistent conservative medical therapy, as evidenced by physician office progress notes, which demonstrates that ≥ 2 of the following having been tried:
 - a. Physical therapy
 - b. Chiropractic care
 - c. Ice/heat therapy
 - d. Pharmacotherapy (e.g., oral/injectable analgesia such as non-steroidal anti-inflammatories, muscle relaxants, epidural/facet injections)

* Discogram is only indicated for the lumbar region.

Limitations/Exclusions

Artificial discs are not considered medically necessary when any of the following are applicable, as there is insufficient evidence to demonstrate therapeutic value/safety:

1. Insertion for purposes for which the device is not FDA approved (off-label use)
2. Insertion despite presence of contraindications identified within the specific product labeling
3. Previous spinal fusion/other spinal surgery at affected level
4. Current or previous fracture at affected level
5. Presence of infection

Revision history

Oct. 8, 2021	Removed prerequisite for grade/millimeter measurement of spondylolisthesis Added the presence of infection as a surgical contraindication
Oct. 12, 2018	Clarified that discogram is only indicated for the lumbar region Removed “No nerve root compression or narrowing of lateral access” as prerequisite
Dec. 9, 2016	Expanded coverage for 1–2 contiguous cervical levels (e.g., Mobi-C®)

Applicable Procedure Codes

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	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), single interspace, lumbar
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)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar

Applicable ICD-10 Diagnosis Codes

M47.16	Other spondylosis with myelopathy, lumbar region
M47.26	Other spondylosis with radiculopathy, lumbar region
M47.27	Other spondylosis with radiculopathy, lumbosacral region
M47.816	Spondylosis without myelopathy or radiculopathy, lumbar region
M47.817	Spondylosis without myelopathy or radiculopathy, lumbosacral region
M47.896	Other spondylosis, lumbar region
M47.897	Other spondylosis, lumbosacral region
M48.36	Traumatic spondylopathy, lumbar region
M48.37	Traumatic spondylopathy, lumbosacral region
M50.00	Cervical disc disorder with myelopathy, unspecified cervical region

M50.01	Cervical disc disorder with myelopathy, high cervical region
M50.020	Cervical disc disorder with myelopathy, mid-cervical region, unspecified level
M50.021	Cervical disc disorder at C4-C5 level with myelopathy
M50.022	Cervical disc disorder at C5-C6 level with myelopathy
M50.023	Cervical disc disorder at C6-C7 level with myelopathy
M50.10	Cervical disc disorder with radiculopathy, unspecified cervical region
M50.11	Cervical disc disorder with radiculopathy, high cervical region
M50.120	Mid-cervical disc disorder, unspecified
M50.121	Cervical disc disorder at C4-C5 level with radiculopathy
M50.122	Cervical disc disorder at C5-C6 level with radiculopathy
M50.123	Cervical disc disorder at C6-C7 level with radiculopathy
M50.20	Another cervical disc displacement, unspecified cervical region
M50.21	Another cervical disc displacement, high cervical region
M50.220	Other cervical disc displacement, mid-cervical region, unspecified level
M50.221	Other cervical disc displacement at C4-C5 level
M50.222	Other cervical disc displacement at C5-C6 level
M50.223	Other cervical disc displacement at C6-C7 level
M50.30	Other cervical disc degeneration, unspecified cervical region
M50.31	Other cervical disc degeneration, high cervical region
M50.320	Other cervical disc degeneration, mid-cervical region, unspecified level
M50.321	Other cervical disc degeneration at C4-C5 level
M50.322	Other cervical disc degeneration at C5-C6 level
M50.323	Other cervical disc degeneration at C6-C7 level
M50.80	Other cervical disc disorders, unspecified cervical region
M50.81	Other cervical disc disorders, high cervical region
M50.820	Other cervical disc disorders, mid-cervical region, unspecified level
M50.821	Other cervical disc disorders at C4-C5 level
M50.822	Other cervical disc disorders at C5-C6 level
M50.823	Other cervical disc disorders at C6-C7 level
M50.90	Cervical disc disorder, unspecified, unspecified cervical region
M50.91	Cervical disc disorder, unspecified, high cervical region
M50.920	Unspecified cervical disc disorder, mid-cervical region, unspecified level
M50.921	Unspecified cervical disc disorder at C4-C5 level
M50.922	Unspecified cervical disc disorder at C5-C6 level

M50.923	Unspecified cervical disc disorder at C6-C7 level
M51.06	Intervertebral disc disorders with myelopathy, lumbar region
M51.16	Intervertebral disc disorders with radiculopathy, lumbar region
M51.17	Intervertebral disc disorders with radiculopathy, lumbosacral region
M51.26	Other intervertebral disc displacement, lumbar region
M51.27	Other intervertebral disc displacement, lumbosacral region
M51.36	Other intervertebral disc degeneration, lumbar region
M51.37	Other intervertebral disc degeneration, lumbosacral region
M51.86	Other intervertebral disc disorders, lumbar region
M51.87	Other intervertebral disc disorders, lumbosacral region
Q76.2	Congenital spondylolisthesis

References

FDA. Medical Devices activL® Artificial Disc – P120024. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P120024>. Accessed November 16, 2023.

FDA. Medical Devices BRYAN® Cervical Disc - P060023. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P060023>. Accessed November 16, 2023.

FDA. Medical Devices CHARITÉ™ Artificial Disc - P040006. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P040006>. Accessed November 16, 2023.

FDA. Medical Devices M6-C™ Artificial Cervical Disc - P170036. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P040006>. Accessed November 16, 2023.

FDA Medical Devices mobi-C® Cervical Disc Prosthesis – P11002. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P110002>. Accessed November 16, 2023.

FDA Medical Devices PCM Cervical Disc System - P100012. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100012>. Accessed November 16, 2023.

FDA Medical Devices PRODISC C® Disc System - P070001. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P070001S007>. Accessed November 16, 2023.

FDA. Medical Devices. PRODISC®-L Total Disc Replacement - P050010. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P050010>. Accessed November 16, 2023.

FDA. Medical Devices. SECURE®-C Artificial Cervical Disc – P100003. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P060018>. Accessed November 16, 2023.

FDA. Medical Devices. Prestige LP Cervical Disc - P090029. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cm?id=P100012>. Accessed November 16, 2023.

FDA. Medical Devices. Prestige Cervical Disc System - P060018. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P060018>. Accessed November 16, 2023.

FDA. Medical Devices. Secure-C Artificial Cervical Disc - P100003. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P100003>. Accessed November 16, 2023.

Comparison of anterior cervical discectomy and fusion versus artificial disc replacement for cervical spondylotic myelopathy: a meta-analysis. Chang CJ, Liu YF, Hsiao YM, Huang YH, Liu KC, Lin RM, Lin CL. J Neurosurg Spine. 2022 Apr 22;1-10. doi: 10.3171/2022.2.SPINE211500. PMID: 35453110

Peng Z, Hong Y, Meng Y, Liu H. Int Orthop. 2022 Jul;46(7):1609-1625. doi: 10.1007/s00264-022-05318-z. Epub 2022 Feb 3. PMID: 35113188

Spine Universe. Spondylolisthesis: Back Condition and Treatment.

<https://www.spineuniverse.com/conditions/spondylolisthesis/spondylolisthesis-back-condition-treatment>. Mar. 2019. Accessed November 16, 2023.

Specialty-matched clinical peer review.