Artificial Intervertebral Discs

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Medical Guideline Disclaimer

 The treating physician or primary care provider must submit to EmblemHealth the clinical evidence that the patient meets the criteria for the treatment or surgical procedure. Without this documentation and information, EmblemHealth will not be able to properly review the request for prior authorization. The clinical review criteria expressed below reflects how EmblemHealth determines whether certain services or supplies are medically necessary. EmblemHealth established the clinical review criteria based upon a review of currently available clinical information (including clinical outcome studies in the peer-reviewed published medical literature, regulatory status of the technology, evidence-based guidelines of public health and health research agencies, evidence-based guidelines and positions of leading national health professional organizations, views of physicians practicing in relevant clinical areas, and other relevant factors). EmblemHealth expressly reserves the right to revise these conclusions as clinical information changes, and welcomes further relevant information. Each benefit program defines which services are covered. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered and/or paid for by EmblemHealth, as some programs exclude coverage for services or supplies that EmblemHealth considers medically necessary. If there is a discrepancy between this guideline and a member's benefits program, the benefits program will govern. In addition, coverage may be mandated by applicable legal requirements of a state, the Federal Government or the Centers for Medicare & Medicaid Services (CMS) for Medicare and Medicaid members. All coding and web site links are accurate at time of publication. EmblemHealth Services Company LLC, ("EmblemHealth") has adopted the herein policy in providing management, administrative and other services to HIP Health Plan of New York, HIP Insurance Company of New York, Group Health Incorporated and GHI HMO Select, related to health benefit plans offered by these entities. All of the aforementioned entities are affiliated companies under common control of EmblemHealth Inc.

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 in order 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): 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: 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.

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)

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)
	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	DDD (L4–L5 or L5–S1): No ≥ Grade I spondylolisthesis at the involved level (single level)
	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 critera 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. No nerve root compression or narrowing of lateral recess
5. Grade/millimeter measurement of spondylolisthesis is commensurate with the FDA-approved indication specific to disc (as variance exists among devices)
6. Pain score ≥ 40 on Visual Analog Scale (VAS)
7. Disability score ≥ 30 on Oswestry Low Back Pain Disability Questionnaire or Neck Disability Index
8. 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)

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

Revision history

12/9/2016 — 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 osteophytectomy 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 osteophytectomy 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
~~M50.02~~	~~Cervical disc disorder with myelopathy, mid-cervical region~~ (Incomplete code 10/01/2016)
M50.020	Cervical disc disorder with myelopathy, mid-cervical region, unspecified level (Eff. 10/01/2016)
M50.021	Cervical disc disorder at C4-C5 level with myelopathy (Eff. 10/01/2016)

M50.022	Cervical disc disorder at C5-C6 level with myelopathy (Eff. 10/01/2016)
M50.023	Cervical disc disorder at C6-C7 level with myelopathy (Eff. 10/01/2016)
M50.10	Cervical disc disorder with radiculopathy, unspecified cervical region
M50.11	Cervical disc disorder with radiculopathy, high cervical region
~~M50.12~~	~~Cervical disc disorder with radiculopathy, mid-cervical region~~ (Incomplete code 10/01/2016)
M50.120	Mid-cervical disc disorder, unspecified (Eff. 10/01/2016)
M50.121	Cervical disc disorder at C4-C5 level with radiculopathy (Eff. 10/01/2016)
M50.122	Cervical disc disorder at C5-C6 level with radiculopathy (Eff. 10/01/2016)
M50.123	Cervical disc disorder at C6-C7 level with radiculopathy (Eff. 10/01/2016)
M50.20	Other cervical disc displacement, unspecified cervical region
M50.21	Other cervical disc displacement, high cervical region
~~M50.22~~	~~Other cervical disc displacement, mid-cervical region~~ (Incomplete code 10/01/2016)
M50.220	Other cervical disc displacement, mid-cervical region, unspecified level (Eff. 10/01/2016)
M50.221	Other cervical disc displacement at C4-C5 level (Eff. 10/01/2016)
M50.222	Other cervical disc displacement at C5-C6 level (Eff. 10/01/2016)
M50.223	Other cervical disc displacement at C6-C7 level (Eff. 10/01/2016)
M50.30	Other cervical disc degeneration, unspecified cervical region
M50.31	Other cervical disc degeneration, high cervical region
~~M50.32~~	~~Other cervical disc degeneration, mid-cervical region~~ (Incomplete code 10/01/2016)
M50.320	Other cervical disc degeneration, mid-cervical region, unspecified level (Eff. 10/01/2016)
M50.321	Other cervical disc degeneration at C4-C5 level (Eff. 10/01/2016)
M50.322	Other cervical disc degeneration at C5-C6 level (Eff. 10/01/2016)
M50.323	Other cervical disc degeneration at C6-C7 level (Eff. 10/01/2016)
M50.80	Other cervical disc disorders, unspecified cervical region
M50.81	Other cervical disc disorders, high cervical region
~~M50.82~~	~~Other cervical disc disorders, mid-cervical region~~ (Incomplete code 10/01/2016)
M50.820	Other cervical disc disorders, mid-cervical region, unspecified level (Eff. 10/01/2016)
M50.821	Other cervical disc disorders at C4-C5 level (Eff. 10/01/2016)
M50.822	Other cervical disc disorders at C5-C6 level (Eff. 10/01/2016)
M50.823	Other cervical disc disorders at C6-C7 level (Eff. 10/01/2016)
M50.90	Cervical disc disorder, unspecified, unspecified cervical region
M50.91	Cervical disc disorder, unspecified, high cervical region
~~M50.92~~	~~Cervical disc disorder, unspecified, mid-cervical region~~ (Incomplete code 10/01/2016)
M50.920	Unspecified cervical disc disorder, mid-cervical region, unspecified level (Eff. 10/01/2016)

M50.921	Unspecified cervical disc disorder at C4-C5 level (Eff. 10/01/2016)
M50.922	Unspecified cervical disc disorder at C5-C6 level (Eff. 10/01/2016)
M50.923	Unspecified cervical disc disorder at C6-C7 level (Eff. 10/01/2016)
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. Guidance for Industry and FDA Staff: Preparation and Review of Investigational Device Exemption Applications (IDEs) for Total Artificial Discs. 2008. Available at: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071154.htm. Accessed September 18, 2017.

FDA. Medical Devices activL® Artificial Disc – P120024 - http://www.fda.gov/medicaldevices/productsandmedicalprocedures/deviceapprovalsandclearances/recently-approveddevices/ucm455656.htm. Accessed September 18, 2017.

FDA. Medical Devices BRYAN® Cervical Disc - P060023. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm162968.htm. Accessed September 18, 2017.

FDA. Medical Devices CHARITÉ™ Artificial Disc - P040006. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm080693.htm. Accessed September 18, 2017.

FDA Medical Devices mobi-C®. Summary and Effectiveness Data. http://www.accessdata.fda.gov/cdrh_docs/pdf11/P110009B.pdf. Accessed September 18, 2017.

FDA Medical Devices PCM Cervical Disc System - P100012. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p100012. Accessed September 18, 2017.

FDA Medical Devices Prestige® Cervical Disc System. http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftopic/pma/pma.cfm?num=p070001 . Accessed September 18, 2017.

FDA. Medical Devices. PRODISC®-L Total Disc Replacement - P050010. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm077620.htm. Accessed September 18, 2017.

FDA. Medical Devices. SECURE®-C Artificial Cervical Disc – P100003. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm322270.htm. Accessed September 18, 2017.

Specialty-matched clinical peer review.

Spine Universe. Spondylolisthesis: Back Condition and Treatment. http://www.spineuniverse.com/conditions/spondylolisthesis/spondylolisthesis-back-condition-treatment. 2016. Accessed September 18, 2017.