Intervertebral Disc Prosthesis

Total Disc Arthroplasty

Date of Origin: 12/2004 **Last Review Date: 05/24/2023** **Effective Date: 06/01/2023**

Dates Reviewed: 01/2005, 01/2006, 11/2006, 08/2007, 08/2008, 12/2009, 02/2011, 02/2012, 11/2013, 08/2014, 11/2015, 11/2016, 08/2017, 05/2018, 06/2019, 06/2020, 06/2021, 05/2022, 05/2023

Developed By: Medical Necessity Criteria Committee

I. Description

When conservative treatment of degenerative disc disease is not effective, a spinal fusion and/or discectomy are commonly performed. A variety of prosthetic intervertebral discs have been investigated over the past few decades as an alternative to spinal fusion. Total disc replacement or spinal arthroplasty is intended to maintain motion at the operative level once the damaged disc has been removed. The prosthetic disc is intended to restore or preserve the natural biomechanics of the intervertebral segment and to reduce further degeneration of adjacent levels.

Artificial intervertebral discs have been used internationally for many years. The first artificial disc to receive FDA approval in the United States was the SB Charite® III lumbar disc. The Charite® was approved on October 26, 2004. A second lumbar artificial disc, the ProDisc®-L Total Disc Replacement, received FDA approval on August 14, 2006. The Charite® lumbar disc has since been pulled from the market and replaced with the INMOTION® artificial lumbar disc. Several other lumbar artificial discs have been developed without FDA approval. Long term clinical outcome of lumbar disc replacement is unclear. Evidence from long-term studies shows potential degeneration of the adjacent discs and facets and wear of the polyethylene part of the disc occurring, requiring revision surgery in some cases.

The first artificial cervical disc to receive FDA approval is the Prestige Cervical Disc System which was approved on July 16, 2007. A second artificial cervical disc, the ProDisc®-C Total Disc Replacement, received FDA approval on December 17, 2007. Examples of other prosthetic intervertebral discs are the Maverick artificial disc prosthesis, the BRYAN® disc, Mobi-C®, SECURE®-C, and Prestige®-LP. See the chart below for FDA approval status of specific devices.

II. Criteria: CWQI HCS-0042A

A. Intervertebral disc prosthesis is medically necessary for **1 or more of the following** indications:
   a. FDA approved **cervical prosthetic discs** (See addendum 3) will be covered to plan limitations when **ALL** of the following criteria are met:
      i. The patient is 18 years of age or older and skeletally mature; and
      ii. Diagnosis of degenerative cervical disc disease or disc herniation at only **one** or two contiguous levels in the cervical spine between C3-C7.

iii. Request for disc replacement in the cervical spine between C3-C7 with FDA approved device for 1 or more of the following:
    1. **single level**;
    2. **two level (Mobi-C® only)**
iv. MRI or CT scan with confirmation of degenerative disc disease with severe spinal stenosis, cord compression, or nerve root compression performed within the last 6 months and **1 or more** of the following:
    1. Herniated disc
    2. Spondylosis, defined as the presence of osteophytes
v. Patient suffers from neck pain of discogenic origin or radiculopathy that has not responded to at least 2 months of conservative treatment *(time frame can be waived if the patient is experiencing progressive neurological worsening despite non operative treatment)* with **2 or more** of the following:
    1. NSAIDs, analgesics, steroids
    2. Physical therapy
    3. Epidural steroid injection/selective nerve root blocks with less than clinically meaningful improvement.
vi. No previous surgical intervention at the involved level(s) or planned procedures at adjacent levels.
vii. Patient also meets **1 or more** of the following:
    1. Patient is a non-smoker
    2. Patient is a documented smoker and has abstained from tobacco for at least 6 weeks prior to surgery as evidenced by lab results documenting nicotine-free status (cotinine level).
viii. The requested intervertebral disc prosthesis is NOT covered if any of the following contraindications are present:
    1. More than one or two cervical level(s) requiring surgical treatment
    2. Fused level adjacent to the level to be treated or planned fusion at an adjacent level with the disc replacement procedure.
    3. Evidence of cervical instability on dynamic flexion-extension radiographs, sagittal-plane translation of greater than 3.5mm, or sagittal-plane angulation of great than 20º at a single level
    4. Diagnosis of osteoporosis, osteopenia or osteomalacia
    5. Spinal metastases
    6. Severe facet joint disease at the involved level
    7. Active systemic infection
    8. Known allergy or sensitivity to stainless steel, titanium or a titanium alloy
    9. Chronic steroid use
    10. Pregnant
    11. Morbid obesity

b. FDA-approved **lumbar prosthetic intervertebral discs** (See addendum 3) will be covered to plan limitations when **ALL** of the following criteria are met:
    i. The patient is skeletally mature; and

ii. Diagnosis of degenerative disc disease at only one level (L4-L5 or L5-S1), confirmed by patient history and advanced imaging studies (CT scan or MRI) within the last 6 months; and
iii. Disc replacement is planned for **one** level; and
iv. No more than Grade I spondylolisthesis at the involved level; and
v. Patient suffers from low back pain that has not responded to at least 6 months of conservative treatment *(time frame can be waived if the patient is experiencing progressive neurological worsening despite non operative treatment)* including **All** of the following:
    1. NSAIDs, analgesics, steroids
    2. Physical therapy
    3. Epidural steroid injections/selective nerve root blocks
vi. Patient is a candidate for spine surgery (such as a fusion); and
vii. No prior lumbar spinal fusion
viii. Patient also meets 1 or more of the following criteria:
    1. Patient is a non-smoker
    2. Patient is a documented smoker and has abstained for at least 6 weeks prior to surgery as evidenced by lab results documenting nicotine-free status *(cotinine level).*
ix. The requested intervertebral disc prosthesis is **NOT** covered if any of the following contraindications are present:
    1. Previous lumbar fusion
    2. Simultaneous multilevel implantations are planned.
    3. Osteoporosis or osteopenia
    4. Imaging studies confirm **1 or more** of the following:
        a. Infection *(active systemic or localized to the site of implantation)*
        b. Spinal tumor
        c. Multiple levels of degenerative disc disease
        d. Degenerative spondylolisthesis of Grade 2 or greater
        e. Par interarticularis defect with either spondylolysis or isthmic spondylolisthesis
        f. Presence of facet ankylosis or Severe facet joint arthrosis
        g. Nerve root compression or lumbar spinal stenosis
        h. Lumbar Scoliosis
        i. Spinal fracture
    5. History of chronic steroid use
    6. Pregnancy
    7. Morbid obesity
    8. Known allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)

B. **<u>Limitations:</u>**
    a. Authorization requests for surgery that involve intervertebral disc devices that are being studied in a clinical trial will be reviewed on a case-by-case basis. The intervertebral disc prosthesis itself that is being studied in the clinical trial is considered investigational and will not be covered by Moda Health. The cost of the artificial disc is usually paid for by the trial.

b. Moda Health considers all other indications for prosthetic intervertebral disc prosthesis experimental and investigational.

III. Information Submitted with the Prior Authorization Request:

1. Chart notes for the treating physician including radiographic studies and conservative treatment attempts and the type of artificial disc being requested.

IV. CPT or HCPC codes covered:

Codes	Description
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	Second level, cervical
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (List separately in addition to code for primary procedure)
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, lumbar, single interspace
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (List separately in addition to code for primary procedure)
0163T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), each additional interspace, lumbar (list separately in addition to code for primary procedure)
0164T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)

V. Annual Review History

Review Date	Revisions	Effective Date
12/2012	Annual Review: Added table with review date, revisions, and effective date.	01/01/2013

11/13	Annual Review: No changes	11/27/2013
09/2014	Annual Review: No changes	09/30/2014
12/2015	Annual Review: Added additional criteria for cervical for imaging studies, added description of lumbar disc replacement studies, added chart with FDA status of devices	12/2015
11/2016	Annual Review: Added criteria regarding smoking cessation prior to surgery, added ICD-10 codes	11/30/2016
08/2017	Annual Review: Added Activ-L lumbar disc as an FDA approved device.	08/23/2017
05/2018	Annual Review: updated criteria for cervical disc replacement to 2 levels with Mobi-C only. Revised conservative therapy for cervical to 2 or more instead of all of the following.	05/23/2018
06/2019	Annual Review: No changes	07/01/2019
06/2020	Annual Review: Updated FDA approval status for M6®-C cervical disc. No content changes	07/01/2020
06/2021	Annual Review: No content changes	07/01/2021
05/2022	Annual Review: Aligned requirements with eviCore	06/01/2022
02/2023	Update: New cpt code 22860 added	
05/2023	Annual Review: Aligned requirements with eviCore	06/01/2023

VI. References

1. Artificial total disc replacement for the lumbar spine. Hayes Alert. Vol. VI, No. 9. September 2003.
2. Bertagnoli R, Yue JJ, Shah RV, et al. The treatment of disabling single-level lumbar discogenic low back pain with total disc arthroplasty utilizing the Prodisc prosthesis: a prospective study with 2-year minimum follow-up. Spine. 2005 Oct 1:30(19):2230-6.
3. Beyond spinal fusion: CINN tests the new artificial disc. Chicago Institute of Neurosurgery and
4. Chang UK, Kim DH, Lee MC, et al. Range of motion change after cervical arthroplasty with ProDis-C and prestige artificial discs compared with anterior cervical discectomy and fusion. J Neurosurg Spine. 2007 Jul;7(1):40-6.
5. Cunningham BW. Basic scientific considerations in total disc arthroplasty. Spine Journal. Nov-Dec
6. Geisler FH, Blumenthal SL, Guyer RD, et al. Neurological complications of lumbar artificial disc
7. German JW, Foley KT. Disc arthroplasty in the management of the painful lumbar motion segment. Spine. 2005 Aug 15;30(16 Suppl): S60-7.
8. Guyer RD, McAfee PC, Hochschuler SH, et al. Prospective randomized study of the Charite artificial disc: data from two investigational centers. Spine Journal. Nov-Dec. 2004;4(6Suppl): S252-9.
9. Lamaire JP. SB Charite III intervertebral disc prosthesis: biomechanical, clinical, and radiological literature: results of a multicenter, prospective, randomized investigational device exemption study
10. McAffee PC, Fedder IL, Saiedy S, et al. Experimental design of total disk replacement-experience with a prospective randomized study of the SB CharitA. Spine. Oct. 2003;25(20): S153-62.
11. Mummaneni PV, Burkus JK, Haid RW, et al. Clinical and radiographic analysis of cervical disc arthroplasty compared with allograft fusion: a randomized controlled clinical trial. J Neurosurg: Spine. 2007 Mar; 6:198-209.
12. Siepe CJ, Mayer HM, Wiechert K, Korge A. Clinical results of total lumbar disc replacement with ProDisc II: three-year results for different indications. Spine. 2006 Aug 1;31(17):1923-32.

13. Spine-health.com, Charite artificial disc; Total disc replacement-Charite artificial disc. Accessed website Nov. 9, 2004.
14. Traynelis VC, Treharne RW. Use of prestige (Prestige ((R)) LP artificial cervical disc in the spine. Expert Rev Med Devices. 2007 Jul;4(4):437-40.
15. Tropiano P, Huang RC, Girardi FP, et al. Lumbar total disc replacement. Surgical technique. J Bone Joint Surg Am. 2006 Mar;88 Suppl 1 Pt 1:50-64.
16. Tropiano P, Huang RC, Girardi FP, Marnay T. Lumbar disc replacement: preliminary results with ProDisc II after minimum follow-up period of 1 year. J Spinal Disord Tech. 2003 Aug;16(4):362-8.
17. Zeller JL. Artificial spinal disk superior to fusion for treating degenerative disk disease. JAMA. December 13, 2006. 2986(22):2665-2667.
18. Sasso RC, Smucker JD, Hacker RJ, Heller JG. Artificial disc versus fusion: a prospective, randomized study with 2-year follow-up on 99 patients. Spine (Phila Pa 1976) 2007; 32:2933.
19. Berg S, Tullberg T, Branth B, et al. Total disc replacement compared to lumbar fusion: a randomized controlled trial with 2-year follow-up. Eur Spine J 2009; 18:1512.
20. Zigler J, Delamarter R, Spivak JM, et al. Results of the prospective, randomized, multicenter Food and Drug Administration investigational device exemption study of the ProDisc-L total disc replacement versus circumferential fusion for the treatment of 1-level degenerative disc disease. Spine (Phila Pa 1976) 2007; 32:1155.
21. Physician Advisors

Appendix 1 – Applicable ICD10 codes:

Codes	Description
G54.2	Cervical root disorders, not elsewhere classified [nerve root/spinal cord compression]
G54.9	Nerve root and plexus disorder, unspecified [nerve root/spinal cord compression]
M50.00 - M50.03	Cervical disc disorder with myelopathy [nerve root/spinal cord compression]
M50.10 - M50.13	Cervical disc disorder with radiculopathy [nerve root/spinal cord compression]
M50.20 - M50.23	Other cervical disc displacement
M50.30 - M50.33	Other cervical disc degeneration
M51.36	Other intervertebral disc degeneration, lumbar region
M51.37	Other intervertebral disc degeneration, lumbosacral region
M53.1	Cervicobrachial syndrome [with findings of weakness, myelopathy, or sensory deficit]

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	NCD/LCD Document (s):
Decision Memo for Lumbar Artificial Disc Replacement (CAG-00292N)	
https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=170&bc=AAAAAAAAEAAA&	

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC

Appendix 3 – Artificial Disc Brands FDA approval status:

Artificial Cervical Discs		
Device Name	**Manufacturer**	**FDA Approval Status**
Advent®	Orthofix®	No
BRYAN® disc	Medtronic	Yes – single level
Cadisc™ -C	Rainier® Technology	No
Cervicare (metal on metal-cobalt-chromium-molybdenum)	Stryker	No – IDE status revoked by FDA
Discover™ (polyethylene on titanium alloy)	DePuy Synthes – (formerly DePuy Spine, Inc.)	No – IDE only
Freedom® Cervical Disc	AxioMed®	No
Kineflex® -C (cobalt-chromium-molybdenum)	SpinalMotion	No – IDE only
M6®-C	Spinal Kinetics™	Yes -Single level
Mobi-C®	LDR Spine USA	Yes - 1 and 2 level
NeoDisc®	NuVasive®	No – IDE only
PCM® (Porous Coated Motion) Cervical Disc (polyethylene-on-metal)	Cervitech, now part of NuVasive®	Yes – Single Level
Prestige® Cervical Disc System (includes Prestige ST (titanium and ceramic)	Medtronic	Yes - Single Level
Prestige® LP Cervical Disc	Medtronic	Yes – Single Level
ProDisc® - C	DePuy Synthes	Yes – Single Level
SECURE® - C	Globus Medical	Yes – Single Level

Artificial Lumbar Disc FDA Approval Status		
Device Name	**Brand**	**FDA Approval Status**

Activ-L™	Aesculap®	Yes – single level
Cadisc™ - L	Rainier® Technology	No
~~Charite®~~	~~DePuy Spine, Inc.~~	Withdrawn from Market
FlexiCore®	Stryker	No
Freedom® Lumbar Disc (FLD)	AxioMed®	No
INMOTION® (formerly Charite®)	DePuy Spine™	Yes – Single Level. This device is a modification of the Charite design
Kineflex-L™ metal-on-metal	SpinalMotion	No
M6® - L	Spinal Kinetics™	No
Maverick®	Medtronic	No
ProDisc® - L	DePuy Synthes	Yes – Single Level
XL TDR®	NuVasive®	No