MedStar Health, Inc. POLICY AND PROCEDURE MANUAL

Policy Number: PA.135.MH Last Review Date: 11/08/2018 Effective Date: 01/01/2018

PA.135.MH – Cervical and Lumbar Artificial Disc Replacement

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers **Artificial Intervertebral Disc Replacement of the Cervical and Lumbar spine for the treatment of Degenerative Disc Disease (DDD)** medically necessary for the following indications:

- 1. The patient is skeletally mature
- 2. Patient has undergone at least six months of non-surgical treatment (including physical therapy, pain medication, or back bracing, without showing improvement) and has not experienced relief of low-back pain symptoms
- 3. The prosthesis used is a Food and Drug Administration (FDA) approved device

AND

Lumbar Artificial Disc Replacement (LADR) using the ProDisc-L Total Disc Replacement device is indicated for coverage when:

- 1. Patient has been diagnosed with single-level DDD at the lumbar spine (L3-S1).
- 2. Patient has no more than Grade 1 spondylolisthesis at the involved level
- 3. Patient has no evidence of malignancy at affected level, no deformity at the level

Cervical Total Disc Replacement using an FDA approved device is indicated for coverage when:

- Patient experiences disc degeneration of no more than one disc in the cervical spine
- Patient has intractable radiculopathy (arm pain and/or neurological deficit with or without neck pain) and/or myelopathy (abnormality localized to the level of the disc space) due to neural compression C3-C7 at one level or two continuous levels

A. Limitations

Limitations to artificial *lumbar* disc replacement include:

- 1. No signs of whole body infection (eg pneumonia), osteoporosis, or arthritis.
- 2. No known allergies to cobalt, chromium, molybdenum, polyethylene, or titanium.

Limitations to artificial *cervical* disc replacement include:



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- 1. No signs of whole body infection (eg pneumonia), osteoporosis, arthritis, or osteomalacia.
- 2. No known allergies to stainless steel.

Background

Degenerative Disc Disease (DDD) is defined by the Food and Drug Administration (FDA) as discogenic back pain (pain resulting from a degenerated intervertebral disc) with degeneration of the disc confirmed by patient history and radiographic studies. Although intervertebral disc degeneration is common with age, it can vary in progression and severity. Isolated pain of the lower lumbar region is a common symptom associated with DDD. A diagnosis of DDD can be completed with patient history, a physical examination, and Magnetic Resonance Imaging (MRI). DDD is typically managed using conservative treatments such as physical therapy, anti-inflammatory drugs, epidural steroid injections, exercise, and massage therapy among other therapies. Spinal fusion surgery may be used to treat DDD in patients who fail conservative treatments. Concerns regarding loss of motion with spinal fusion therapy lead to the development of an alternative artificial disc replacement therapy intended to preserve spinal motion. The intended outcomes of artificial disc replacement are to reduce pain, repair intervertebral disc height and preserve motion at the point of surgery.

ProDisc-L Total Disc Replacement is an artificial disc intended for use in LADR that was FDA approved in 2006. The device is used to replace damaged intervertebral discs with the goal of reducing pain and allowing movement at the spinal level where the disc was implanted. The FDA has approved 4 cervical disc prostheses including the Prestige Cervical Disc Systems, the ProDisc-C Total Disc Replacement, the Bryan Cervical Disc System, and the Mobi-C Cervical Disc.

Codes: CPT HCPCS

Code	Description
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical
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)



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0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar
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)
0375T	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection), cervical, three or more levels
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
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
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar
22612	Arthrodesis, posterior or posterolateral technique, single level; lumbar (with or without lateral transverse technique)
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace; lumbar
22865	Spinal Instrumentation Procedures on the Spine (Vertebral Column)

References

1. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) No 150.10 – Lumbar Artificial Disc Replacement (LADR). Effective date 8/14/2007. https://www.cms.gov/medicare-coverage-



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- 3. U.S. Food and Drug Administration (FDA). Medical Devices: ProDisc-L Total Disc Replacement-https://www.accessdata.fda.gov/cdrh_docs/pdf5/P050010c.pdf
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- 5. Hayes Medical Technology Directory. Comparative Effectiveness Review Multilevel Artificial Disc Replacement for Cervical Degenerative Disc Disease. Publication Date: 10/03/2017.
- Hayes Medical Technology Directory. Comparative Effectiveness Review Single Level Artificial Disc Replacement for Cervical Degenerative Disc Disease. Publication Date: 08/21/2017. Annual Review Date: 08/28/2018.
- 7. American Association of Neurological Surgeons. Artificial Lumbar Disc. 2018. http://www.aans.org/Patient%20Information/Conditions%20and%20Treatments/Artificial%20Lumbar%20Disc.aspx
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- 10. Medtronic Cervical Herniated Disc. Prestige Cervical Disc. http://www.medtronic.com/patients/cervical-herniated-discs/device/our-artificial-disc/prestige/. Last updated August 2018.
- 11. Mobi-C Cercial Disc. http://www.cervicaldisc.com/. 2018.

Disclaimer:

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