

MedStar Health, Inc.

POLICY AND PROCEDURE MANUAL

Policy Number: PA.135.MH
Last Review Date: 11/04/2016
Effective Date: 04/15/2017

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

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar MA – DSNP - CSNP

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

NOTE: See Variation section for Medicare age limitation on LADR

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

1. Patient experiences disc degeneration of no more than one disc in the cervical spine
2. 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.

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Limitations to artificial *cervical* disc replacement include:

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

Variations - Medicare

LADR is considered not reasonable and necessary for Medicare members over the age of 60 and is not a covered benefit.

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 |

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| 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 |
| 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 osteophyctomy 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 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 |
| 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

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3. U.S. Food and Drug Administration (FDA). Medical Devices: ProDisc-L Total Disc Replacement- PO50010. Last updated: 09/05/2013. <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm077620.htm>
4. Hayes Medical Technology Directory. Lumbar Total Disc Replacement for Degenerative Disc Disease. Publication Date: 08/13/2015.
5. Hayes Medical Technology Directory. Artificial Disc Replacement for Cervical Degenerative Disc Disease. Last Reviewed 12/11/2015.
6. American Association of Neurological Surgeons. Artificial Lumbar Disc. Publication Date: August 2007. <http://www.aans.org/Patient%20Information/Conditions%20and%20Treatments/Artificial%20Lumbar%20Disc.aspx>
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9. Medtronic Cervical Herniated Disc. Prestige Cervical Disc. <http://www.medtronic.com/patients/cervical-herniated-discs/device/our-artificial-disc/prestige/>. Last updated Oct 8 2012.
10. Mobi-C Cervical Disc. <http://www.cervicaldisc.com/>. 2016.

Disclaimer:

MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable

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Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

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