



MEDICAL COVERAGE POLICY

SERVICE: Artificial Disc Replacement

Policy Number:	061
Effective Date:	04/01/2018
Last Review:	02/20/2018
Next Review Date:	02/20/2019

Important note

Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website.

SERVICE: Lumbar and Cervical Artificial Disc Replacement

PRIOR AUTHORIZATION: Required

POLICY: SWHP may consider artificial disc replacement medically necessary for one-level or contiguous two-level cervical (C3 to C7) artificial intervertebral disc replacement when ALL of the following criteria are met:

1. Degenerative disc disease or herniated disc at one or two contiguous levels from C3 to C7 confirmed by CT or MRI; AND
2. Absence of these contraindications:
 - Infection, systemic or localized to the operative site; OR
 - Allergy or sensitivity to the implant materials; OR
 - Compromised vertebral bodies at the affected level(s) due to the following:
 - Previous trauma to the cervical spine; OR
 - Significant cervical anatomical deformity or disease; OR
 - Marked cervical instability on neutral resting lateral or flexion/extension radiographs; with greater than 3 mm translation or greater than 11 degrees of angular difference to either adjacent level; OR
 - Moderate or severe spondylosis at the level to be treated, characterized by any of the following:
 - Bridging osteophytes; OR
 - Loss of greater than 50% normal disc height; OR
 - Absence of motion less than 2 degrees; OR
 - Osteoporosis or osteopenia with a DEXA bone mineral density T-score ≤ -1.5
 - Severe facet disease or degeneration
3. Presence of neurological deficit (weakness or sensory deficit); AND
4. Intractable neck and radicular arm pain; AND
5. Failure of at least six weeks of conservative treatment (e.g., analgesics, physical therapy)

SWHP may consider lumbar artificial intervertebral disc replacement medically necessary when ALL of the following criteria are met:

1. Degenerative disc disease at ONE SYMPTOMATIC level, L4-5 or L5-S1, confirmed by CT or MRI; AND



MEDICAL COVERAGE POLICY

SERVICE: Artificial Disc Replacement

Policy Number:	061
Effective Date:	04/01/2018
Last Review:	02/20/2018
Next Review Date:	02/20/2019

2. Absence of contraindications listed in section number 2 above; AND
3. Failure of at least six months of conservative treatment; AND
4. No more than grade I spondylolisthesis at the involved level; AND

Commonly used radiographic grading system for spondylolisthesis of Meyerding. See ref 12.

Grade I	25% or less of vertebral body has slipped forward
Grade II	Between 25% and 50% of vertebral body has slipped forward
Grade III	Between 50% and 75% of vertebral body has slipped forward
Grade IV	More than 75% of vertebral body has slipped forward
Grade V	L5 vertebra positioned completely below the top of the sacrum

5. Member has unremitting low back pain and significant and measurable functional impairment.

In addition, for BOTH procedures, the member must be at least 18 years old, and the implant must be FDA-approved and utilized in accordance with FDA labeling.

Medicare does **NOT** cover Lumbar Total Disc Replacement for members 60 years of age and older. There is no National or Local Coverage Determination for members < 60 years of age or for cervical replacement. NCD 150.10

OVERVIEW: Most adults will experience at least one episode of significant back pain at some point in their lives, the majority of which is due to degenerative disc disease (DDD). DDD is the leading cause of pain and disability in the U.S., and is associated with significant socioeconomic impact. Conversely, many individuals with DDD are asymptomatic. Most symptomatic patients are successfully treated conservatively, but some will ultimately require surgical intervention, often involving discectomy and/or fusion.

Artificial disc replacement was developed as an alternative to spinal discectomy and fusion surgery in individuals with DDD which is nonresponsive to conservative therapy. The artificial disc is intended to relieve pain, restore disc height, maintain motion and stability, and prevent degeneration of adjacent discs.

The cervical products are labeled for use in reconstruction of the disc from C3 to C7 in individuals with intractable radiculopathy and/or myelopathy, with documented disc herniation, loss of disc height, spondylosis, and/or osteophyte formation on imaging. The lumbar products are labeled for use in spinal arthroplasty in patients with DDD who have failed conservative treatment.

SWHP considers 1-level lumbar total disc replacement (LTDR) as an alternative to spinal fusion proven for symptomatic degenerative disc disease (DDD), using a Food and Drug Administration (FDA)-approved artificial disc in properly selected patients who have failed conservative treatment – see clinical criteria above. Recent meta-analyses appear to show long-term superiority over spinal fusion across several patient outcomes.

MANDATES: N/A



MEDICAL COVERAGE POLICY

SERVICE: Artificial Disc Replacement

Policy Number:	061
Effective Date:	04/01/2018
Last Review:	02/20/2018
Next Review Date:	02/20/2019

CODES:

Important note:

CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	22856 - Total disc arthroplasty, artificial disc, single interspace, cervical 22858 - Total disc arthroplasty (artificial disc), anterior approach, second level, cervical. 22861 - Revision and replacement, total disc arthroplasty, single interspace, cervical 22864 - Removal of total disc arthroplasty, artificial disc, single interspace, cervical 22857 - Total disc arthroplasty, artificial disc, single interspace, lumbar 22862 - Revision and replacement, total disc arthroplasty, single interspace, lumbar 22865 - Removal of total disc arthroplasty, artificial disc, single interspace, lumbar
CPT Codes: Not Covered	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, each additional interspace, lumbar 0164T - Removal of total disc arthroplasty, artificial disc, each additional interspace, lumbar 0165T - Revision and replacement, total disc arthroplasty, each additional interspace, lumbar 0375T - Total disc arthroplasty cervical, three or more levels
ICD10 Codes	M50.00 - M50.13

CMS: There is no NCD for cervical disc replacement.

See the National Coverage Determination (NCD) for Lumbar Artificial Disc Replacement (LADR) (150.10).

POLICY HISTORY:

Status	Date	Action
New	1/1/2011	New policy
Reviewed	12/2/2011	Reviewed
Reviewed	8/30/2012	Reviewed.
Reviewed	4/25/2013	Significantly revised to include indication for procedure
Reviewed	3/27/2014	No changes.
Reviewed	4/9/2015	No changes.
Reviewed	4/14/2016	Reviewed CMS coverage. No changes.
Reviewed	3/28/2017	Modified criteria to include multi-level cervical.
Reviewed	2/20/2018	Re-wrote criteria for coverage. Confirmed CMS coverage statement. Removed T-codes



MEDICAL COVERAGE POLICY

SERVICE: Artificial Disc Replacement

Policy Number:	061
Effective Date:	04/01/2018
Last Review:	02/20/2018
Next Review Date:	02/20/2019

REFERENCES:

1. American Association of Neurological Surgeons (AANS) Website. Artificial Cervical Disc. www.aans.org, accessed December 6, 2010.
2. American Association of Neurological Surgeons (AANS) Website. Artificial lumbar disc. www.aans.org, accessed December 6, 2010.
3. American Association of Neurological Surgeons (AANS) Website. Health information you should know: artificial disc – an alternative to spinal fusion surgery – candidates for this surgery must meet specific criteria. www.aans.org, accessed December 6, 2010.
4. Chou R, Loeser J, Owens D, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain. *Spine*, 2009; 34: 1066-1077.
5. Hayes Directory Report, Artificial Disc Replacement for Cervical Degenerative Disc Disease, August 9, 2010.
6. Hayes Directory Report, Lumbar Total Disc Replacement for Degenerative Disc Disease, April 1, 2009, updated April 9, 2010.
7. CMS NCD for Lumbar Artificial Disc Replacement (150.10), August 14, 2007.
8. TrailBlazer Health Enterprises, LCD, Non-Covered Services-4Z-18AB-R17, 4Z-18(L26811), March 1, 2008, revised October 18, 2010.
9. Schaufele M, Walsh A. Lumbar degenerative disease. In: *Frontera: Essentials of Physical Medicine and Rehabilitation*. 2nd ed. Maryland Heights, MO; Saunders: 2008.
10. Up To Date OnLine 18.3. Subacute and Chronic Low Back Pain: Surgical Treatment. Accessed December 6, 2010. www.uptodate.com.
11. Wildstein M, Carragee E. Low Back Pain. In: *Firestein: Kelly's Textbook of Rheumatology*. 8th ed. Maryland Heights, MO; Saunders: 2008.
12. Warner WC, Sawyer JR. Scoliosis and kyphosis. In: Azar FM, Beaty JH, Canale ST. *Campbell's Operative Orthopaedics*. 13th Ed. Philadelphia, PA: Elsevier; 2017:1897-2120.
13. Wei J, Song Y, Sun L, Lv C. Comparison of artificial total disc replacement versus fusion for lumbar degenerative disc disease: a meta-analysis of randomized controlled trials. *Int Orthop*. 2013 Jul;37(7):1315-25. doi: 10.1007/s00264-013-1883-8. Epub 2013 May 4.
14. Zigler JE, et al. Comparison of lumbar total disc replacement with surgical spinal fusion for the treatment of single-level degenerative disc disease: A meta-analysis of 5-year outcomes from randomized controlled trials. *Global Spine Journal*. 2017 Nov. Ahead of Print.