Artificial Intervertebral Disc

DESCRIPTION

Prosthetic intervertebral disc replacement is proposed as an alternative to spinal fusion in individuals with degenerative disc disease. Cervical devices use two metal endplates that are press fit into adjacent vertebrae and a central free component. This central component is held into place by the surrounding normal soft tissues (such as ligaments and the disc annulus) and shifts dynamically within the disc space during spinal motion. These devices are designed to restore disc height and normal physiologic motion. FDA approved devices appropriate for use in single-level cervical disc replacement include M6-C® Artificial Cervical Disc Prosthesis, Bryan® Cervical Disc, Mobi-C® Cervical Disc Prosthesis, PCM® Cervical Disc System, Prestige® Cervical Disc System, ProDisc-C™ Total Disc Replacement, Simplify® Cervical Disc, and Prestige LP® Cervical Artificial Intervertebral Disc. The PRESTIGE® LP, Simplify® Cervical Disc, and MOBI-C® have received FDA approval for implantation at two contiguous cervical levels.

Available FDA approved artificial lumbar disc devices for one level are the activL® and prodisc® L. The prodisc® L has also received FDA approval for treatment of two adjacent levels of the lumbar spine. The Charité® was approved by the FDA through the pre-market process; however, production was stopped in 2010 and the device was withdrawn in 2012.

POLICY

- Artificial intervertebral disc implantation is considered ***medically necessary*** if the medical appropriateness criteria are met. **(See Medical Appropriateness below.)**

- Thoracic artificial intervertebral disc implantation for the treatment of degenerative disc disease, radicular pain and myelopathy is considered ***investigational.***

- Any device utilized for this procedure must have FDA approval specific to the indication, otherwise it will be considered ***investigational*.**

MEDICAL APPROPRIATENESS

- Artificial intervertebral disc implantation is considered **medically appropriate** if **ANY ONE** of the following are met:
  - Cervical artificial intervertebral disc implantation when **ALL** of the following are met:
    - Skeletally mature individual and **ANY ONE** of the following:
      - Degenerative disc disease is affecting one or two contiguous levels from C3-C7
      - One level disc replacement C3-C7 with previous one level fusion at another level
    - Symptoms secondary to spondylotic osteophyte or herniated disc
    - Degenerative disc disease confirmed by magnetic resonance imaging (MRI), computed tomography (CT) or myelography
    - Procedure is indicated for **ANY ONE** of the following:
      - Symptomatic cervical radiculopathy when **ANY ONE** of the following is met:
        - Failure of 6 weeks of conservative treatment under the direction of a physician to include pharmacotherapy and physical therapy
        - Failure to respond to conservative treatment and condition is clinically worsening

- Symptomatic myeloradiculopathy or myelopathy confirmed by imaging, when surgical intervention is justified by severity of disease (e.g., severe or rapidly progressive symptoms of nerve root or spinal cord compression)

- Absence of **ALL** the following contraindications:
  - Planned two-level disc replacement with any prior fused cervical levels
  - Prior cervical fusion at two or more levels
  - Combined use of an artificial cervical disc and fusion
  - Evidence of cervical instability as indicated by **ANY ONE** of the following:
    - Sagittal plane angulation of more than 11 degrees on lateral flexion-extension x-rays
    - Sagittal plane translation of more than 3 mm on lateral flexion–extension x-rays
  - Active systemic infection or localized infection at site of implantation
  - Anatomic deformity at affected level (e.g., ankylosing spondylitis, ossification of posterior longitudinal ligament, previous fracture)
  - Metabolic bone disease (e.g., osteoporosis, osteopenia, osteomalacia)
  - Rheumatoid arthritis
  - Radiographic evidence of moderate or severe and clinically significant facet joint degeneration or disease
  - Active malignancy in the cervical spine
  - Symptomatic disease affecting three or more levels
  - Known hypersensitivity to implant materials
  - Advanced spondylosis (i.e., disc height loss of 50% or more, motion at the symptomatic site is absent on flexion-extension views, presence of bridging osteophytes)

- Revision of cervical artificial intervertebral disc arthroplasty when **ALL** the following are met:
  - Skeletally mature individual and **ANY ONE** of the following:
    - Persistent symptomatic central or foraminal stenosis
    - Imaging evidence of **ANY ONE** of the following:
      - Implant migration
      - Subsidence
      - Endplate failure
      - Loosening
      - Wear
      - Implant malposition
    - Instability
    - Device failure
    - Loss of motion

- Lumbar artificial intervertebral disc implantation when **ALL** of the following are met:
  - Skeletally mature individual
  - Primary complaint of axial pain, with or without lower extremity pain
  - Disc replacement is planned for one or two contiguous levels from L3 to S1 during the same operative session
  - Radiographic evidence of moderate to severe degeneration with Modic changes at level(s) planned for replacement, when compared to other normal or mildly degenerated levels
  - Documentation that symptoms have been present for a minimum of one year
  - Documentation that symptoms interfere with daily activities
  - Presence of chronic pain and functional impairment that has failed to improve with a minimum six months of conservative treatment including **ALL** of the following:
    - Physical therapy/rehabilitation
    - Pain management (e.g., medications, injections)

- Absence of **ALL** the following contraindications:
  - Poorly managed psychiatric disorder
  - Significant facet joint arthropathy at level planned for surgery
  - Active infection (at surgical site or systemic)
  - Active malignancy: A history of any invasive malignancy (except non-melanoma skin cancer), unless treated with curative intent and no clinical signs or symptoms of malignancy for 5 years
  - For treatment of adjacent segment disease with prior fusion or other stabilizing procedure
  - Known hypersensitivity to implant materials (e.g., cobalt, chromium, polyethylene, titanium)
  - Radiographic evidence of moderate or severe facet joint degeneration or disease or pars defect (unilateral or bilateral spondylolysis) at the intended level
  - Symptomatic lumbar spinal stenosis
  - Disc replacement will be performed at the same time as lumbar fusion at another level
  - Osteoporosis or osteopenia (DEXA bone density T-score of less than -1.0)
  - Paget's disease, osteomalacia, or any other metabolic bone disease (excluding osteoporosis which is addressed above)
  - Taking medications or any drug known to potentially interfere with bone/soft tissue healing (e.g., steroids, chemotherapy, dialysis)
  - Rheumatoid arthritis or other autoimmune disease
  - Isolated radicular compression syndromes (including central or far-lateral disc herniation)
  - Traumatic injury at affected level resulting in compromised vertebral bodies
  - Spondylolisthesis greater than 3 mm
  - BMI greater than 40
  - Pregnant or interest in becoming pregnant in the next year
  - Back or leg pain of unknown etiology
  - Chronic pain disorder (e.g., fibromyalgia, failed lower back surgery syndrome, presence of lumbar spinal cord stimulator)

IMPORTANT REMINDERS

- Any specific products referenced in this policy are just examples and are intended for illustrative purposes only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available. These examples are contained in the parenthetical e.g. statement.

- We develop Medical Policies to provide guidance to Members and Providers. This Medical Policy relates only to the services or supplies described in it. The existence of a Medical Policy is not an authorization, certification, explanation of benefits or a contract for the service (or supply) that is referenced in the Medical Policy. For a determination of the benefits that a Member is entitled to receive under his or her health plan, the Member's health plan must be reviewed. If there is a conflict between the medical policy and a health plan or government program (e.g., TennCare), the express terms of the health plan or government program will govern.

SOURCES

Bai, D.Y., Liang, L., Zhang, B.B., Zhu, T., Zhang, H.J., Yuan, Z., & Chen, Y. (2019). Total disc replacement versus fusion for lumbar degenerative diseases - a meta-analysis of randomized controlled trials. *Medicine,* 98 (29), e16460. (Level 1 evidence)

BlueCross BlueShield Association. Evidence Positioning System. (5:2023). *Artificial intervertebral disc: cervical spine* (7.01.108). Retrieved October 25, 2023 from https://www.bcbsaoca.com/eps/. (50 articles and/or guidelines reviewed)

BlueCross BlueShield Association. Evidence Positioning System. (5:2023). *Artificial intervertebral disc: lumbar spine* (7.01.87). Retrieved October 25, 2023 from https://www.bcbsaoca.com/eps/. (24 articles and/or guidelines reviewed)

Blumenthal, S. L., Guyer, R. D., Zigler, J. E., & Ohnmeiss, D. D. (2023). Impact of previous lumbar spine surgery on the outcome of lumbar total disc replacement: analysis of prospective 5-year follow-up study data. *European Spine Journal,* 32 (3), 797–802. (Level 3 evidence)

Burkus, J., Traynelis, V., Haid, R., & Mummaneni, P. (2014). Clinical and radiographic analysis of an artificial cervical disc: 7-year follow-up from the Prestige prospective randomized controlled clinical trial: clinical article. *Journal of Neurosurgery: Spine,* 21 (4), 516-528. (Level 2 evidence)

Centers for Medicare & Medicaid Services. CMS.gov. (2007, October). National Coverage Determination: (*NCD) for lumbar artificial disc replacement (LADR)* (150.10). Retrieved October 3, 2017 from https://www.cms.gov.

CMS.gov: Centers for Medicare & Medicaid Services. Palmetto GBA. (2023, April). *Cervical disc replacement*. (LCD ID L38033). Retrieved October 25, 2023 from https://www.cms.gov.

Cui, X., Li, H-T., Zhang, W., Zhang, L-L., Luo, Z-P., & Yang, H-L. (2018). Mid– to long-term results of total disc replacement for lumbar degenerative disc disease: a systematic review. *Journal of Orthopaedic Surgery and Research,* 13 (26), doi: 10.1186/s13018-018-1032-6. (Level 2 evidence)

Davis, R., Nunley, P., Kim, K., Hisey, M., Jackson, R., Bae, H., et al. (2015). Two-level total disc replacement with Mobi-C cervical artificial disc versus anterior discectomy and fusion: a prospective, randomized, controlled multicenter clinical trial with 4-year follow-up results. *Journal of Neurosurgery: Spine,* 22, 15-25. (Level 2 evidence)

Furunes, H., Storheim, K., Brox, J.I., Johnsen, L.G., Skouen, J.S., Franssen, E., et al. (2017). Total disc replacement versus multidisciplinary rehabilitation in patients with chronic low back and degenerative discs: 8-year follow-up of a randomized controlled multicenter trial. *Spine Journal,* 17 (10), 1480-1488. Abstract retrieved September 7, 2018 from PubMed database.

Gornet, M. F., Burkus, J. K., Shaffrey, M. E., Arqires, P. J., Nian, H., and Harrell, F. E, Jr. (2015). Cervical disc arthroplasty with PRESTIGE LP disc versus anterior cervical discectomy and fusion: a prospective, multicenter investigational device exemption study. *Journal of Neurosurgery: Spine,* 23, 558-573. (Level 3 evidence)

Hollyer, M.A., Gill, E.C., Ayis, S., & Demetriades, A.K. (2020). The safety and efficacy of hybrid surgery for multilevel cervical degenerative disc disease versus anterior cervical discectomy and fusion or cervical disc arthroplasty: a systematic review and meta-analysis. *Acta Neurochirurgica*, 162 (2), 289-303. Abstract retrieved March 29, 2024 from PubMed database.

Joaquim, A. F., Lee, N. J., & Riew, K. D. (2021). Revision surgeries at the index level after cervical disc arthroplasty - a systematic review. *Neurospine,* 18 (1), 34–44. (Level 1 evidence)

Li, Y. Z., Sun, P., Chen, D., Tang, L., Chen, C. H., & Wu, A. M. (2020). Artificial total disc replacement versus fusion for lumbar degenerative disc disease: an update systematic review and meta-analysis. Turkish Neurosurgery, 30 (1), 1–10. Abstract retrieved October 30, 2023 from PubMed database.

Mu, X., Wei, J., Jiancuo, A., Li, Z & Ou, Y. (2018). The short-term efficacy and safety of artificial total disc replacement for selected patients with lumbar degenerative disc disease compared with anterior lumbar interbody fusion: A systematic review and meta-analysis. *PLOS One,* 13 (12), e0209660. (Level 1 evidence)

National Institute for Health and Clinical Excellence (NICE). (2010, May). *Prosthetic intervertebral disc replacement in the cervical spine*. Retrieved June 22, 2010 from http://www.nice.org.uk.

National Institute for Health and Clinical Excellence (NICE). (2009, July). *Prosthetic intervertebral disc replacement in the lumbar spine.* Retrieved June 22, 2010 from http://www.nice.org.uk.

North American Spine Society (NASS). (2010). *Diagnosis and treatment of cervical radiculopathy from degenerative disorders.* Retrieved March 28, 2024 from https://www.spine.org/Research/Clinical-Guidelines.

Radcliff, K., Coric, D., & Albert, T. (2016). Five-year clinical results of cervical total disc replacement compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled, multicenter investigational device exemption clinical trial. *Journal of Neurosurgery: Spine,* 25, 213-224. (Level 2 evidence)

Radcliff, K., Coric, D., & Albert, T. (2016). Replacement compared with anterior discectomy and fusion for treatment of 2-level symptomatic degenerative disc disease: a prospective, randomized, controlled, multicenter investigational device exemption clinical trial. *Journal of Neurosurgery: Spine,* doi: 10.3171/2015.12.SPINE15824. (Level 2 evidence)

Turning Point Healthcare Solutions. (2023, April). *Cervical Disc Arthroplasty.* Retrieved October 24, 2023 from Turning Point Healthcare Solutions.

Turning Point Healthcare Solutions. (2023, April). *Lumbar Disc Replacement.* Retrieved October 24, 2023 from Turning Point Healthcare Solutions.

U. S. Food and Drug Administration. (2007, December). Center for Devices and Radiological Health. *ProDisc™-C Total Disc Replacement. P070001*. Retrieved February 19, 2008 from http://www.accessdata.fda.gov.

U. S. Food and Drug Administration. (2009, May). Center for Devices and Radiological Health. *BRYAN® cervical disc. P060023.* Retrieved July 9, 2010 from http://www.accessdata.fda.gov.

U. S. Food and Drug Administration. (2015, June). Center for Devices and Radiological Health. *Mobi-C® cervical disc. P110002/S012.* Retrieved September 3, 2015 from http://www.fda.gov.

U.S. Food and Drug Administration (2020, April) Center for Devices and Radiological Health. *prodisc® L total disc replacement. P050010/S020.* Retrieved November 2, 2023 from http://www.accessdata.fda.gov.

U.S. Food and Drug Administration. (2016, July). Center for Devices and Radiological Health. *Prestige LP cervical disc P090029/S003.* Retrieved September 8, 2016 from http://www.accessdata.fda.gov.

U.S. Food and Drug Administration. (2020, September). Center for Devices and Radiological Health. *Simplify cervical disc P200022.* Retrieved September 15, 2021 from http://www.accessdata.fda.gov.

U.S. Food and Drug Administration. (2021, April). Center for Devices and Radiological Health. *Simplify cervical disc P200022/S003.* Retrieved September 15, 2021 from http://www.accessdata.fda.gov.

Wahood, W., Yolcu, Y.U., Kerezoudis, P., Goyal, AA, M., Freedman, B.A., & Bydon, M. (2020). Artificial discs in cervical disc replacement: A meta-analysis for comparison of long-term outcomes. *World Neurosurgery,* 134, 5988-613. Abstract retrieved July 16, 2021 from PubMed database.

Winifred S. Hayes, Inc. Comparative Effectiveness Review. (2019, April; last update search March 2022). *Lumbar total disc replacement for degenerative disc disease.* Retrieved October 7, 2022 from www.Hayesinc.com/subscribers. (113 articles and/or guidelines reviewed)

Zavras, A. G., Sullivan, T. B., Singh, K., Phillips, F. M., & Colman, M. W. (2022). Failure in cervical total disc arthroplasty: single institution experience, systematic review of the literature, and proposal of the RUSH TDA failure classification system. *The Spine Journal,* 22 (3), 353–369. Abstract retrieved October 30, 2023 from PubMed database.

Zhang, J., Meng, F., Ding, Y., Li, J., Han, J., Zhang, X., et al. (2020). Comprehensive analysis of hybrid surgery and anterior cervical discectomy and fusion in cervical diseases. *Medicine (Baltimore),* 99 (5), e19055. (Level 1 evidence)

Zigler, J.E., Blumenthal, S.L., Guyer, R.D., Ohnmeiss, D.D., & Patel, L. (2018). Progression of adjacent-level degeneration after lumbar total disc replacement: results of a post-hoc analysis of patients with available radiographs from a prospective study with 5-year follow-up. *Spine,* 43 (20), 1395-1400. (Level 3 evidence)

EFFECTIVE DATE 7/31/2024

ID_BT