Approved Revised: Do Not Implement Until 1/30/27

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 physiological 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, Simplify® Cervical Disc, and Prestige LP® Cervical Artificial Intervertebral Disc. The PRESTIGE® LP, Simplify® Cervical Disc, MOBI-C®, prodisc® C SK, and prodisc® C Vivo have received FDA approval for implantation at one level or two contiguous cervical levels.

Available FDA-approved artificial lumbar disc devices include activL® for one-level use and prodisc® L for one- or two-level use at adjacent levels. 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was approved by the FDA through the pre-market process; however, production was stopped in 2010 and the device was withdrawn in 2012.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
            - One level disc replacement C3-C7 with previous one level cervical disc replacement
            - Two level disc replacement C3-C7 with no simultaneous or previous fusion and no previous cervical disc replacement
        - Symptoms secondary to spinal stenosis 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 (e.g., acetaminophen, NSAIDS, corticosteroids), and physical therapy or a detailed professionally directed home exercise program
- 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 or simultaneous fused cervical level(s)
  - Planned two-level disc replacement with any prior or simultaneous cervical disc replacement
  - Prior cervical fusion at two or more levels
  - Prior cervical disc replacement 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 symptomatic (e.g., pain with extension of joints that is relieved temporarily with injections) 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
    - Infection

- 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 6 months
- 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 or detailed professionally directed home exercise program
  - Analgesics or anti-inflammatory medications (e.g., acetaminophen, NSAIDS, corticosteroids), any route
- 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 4 mm
  - Post laminectomy instability (4mm or greater)
  - 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)

- Revision of lumbar artificial intervertebral disc arthroplasty when **ALL** of 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:
      - Migration
      - Subsidence
      - Endplate failure
      - Loosening
      - Wear
      - Implant malposition
    - Instability

- Device failure
- Loss of motion
- Infection

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.

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