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, and Prestige LP® Cervical Artificial Intervertebral Disc. The PRESTIGE® LP 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 Charité® was approved by the FDA through the pre-market process; however, production was stopped in 2010 and the device was withdrawn in 2012.

The proposal is to add words or statements in red and delete words or statements with a strikethrough.

POLICY

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

- Cervical artificial intervertebral disc implantation at more than two levels is considered investigational.

- Lumbar or 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

- Cervical Artificial intervertebral disc implantation is considered medically appropriate if ALL ANY ONE of the following are met:
  - Cervical artificial intervertebral disc implantation when ALL of the following are met:
    - Procedure can include a single level or the addition of an adjacent level artificial intervertebral disc implantation if ALL of the following are met:
      - Skeletally mature individual
      - Cervical Degenerative disc disease is from affecting one or two contiguous levels from C3-C7
      - Symptoms secondary to spondylotic osteophyte or herniated disc
      - Degenerative disc disease confirmed by magnetic resonance imaging (MRI), computed tomography (CT) or myelography as indicated by ANY ONE of the following findings:
        - Indicated for ANY ONE of the following:
          - Intractable Symptomatic cervical radiculopathy when ANY ONE of the following are met:
          - Severe or rapidly progressive symptoms of nerve root or spinal cord compression requiring hospitalization or immediate surgical treatment
Failure of 6 weeks of conservative nonoperative treatment under the direction of a physician to include pharmacotherapy and physical therapy including, but not limited to, ALL of the following:
- Under the direction of a physician
- Pharmacotherapy that addresses neuropathic pain and other pain sources
- Physical therapy
- Failure to respond to conservative treatment and condition is clinically worsening
- Symptomatic myeloradiculopathy or myelopathy 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:
- Combined use of artificial cervical disc and fusion
- Prior surgery at treated cervical level
- Previous fusion at another cervical level
- Degenerative disease adjacent to a prior cervical 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 3.5 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 or other autoimmune disease
- Presence of facet arthritis
- Radiographic evidence of 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)
- Presence of a previously implanted cervical artificial intervertebral disc device at another level.

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
- Radiographic evidence of moderate to severe single level degeneration at L4-5 or L5-S1 with changes to endplate, 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 of the following contraindications:
- Poorly managed psychiatric disorder
- Significant facet joint arthropathy at level planned for surgery
- Presence of a neoplasm or infection (at surgical site or systemic)
- 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 facet joint degeneration or disease or pars defect

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• Radiographic evidence of multi-level degeneration or bony 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)
• Isolated radicular compression syndromes (including central or far-lateral disc herniation)
• Traumatic injury at affected level resulting in compromised vertebral bodies
• Degenerative or lytic spondylolisthesis greater than Grade 1
• BMI greater than 40

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, the express terms of the health plan will govern.

SOURCES


Policy

Medical Policy Manual

Draft Revised Policy: Do Not Implement


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Medical Policy Manual  Draft Revised Policy: Do Not Implement


EFFECTIVE DATE

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