Subject: Intervertebral Disc Prostheses*

Effective Date: July 26, 2005

Department(s): Utilization Management

Policy: Implantation of intervertebral disc prostheses is reimbursable under Plans administered by QualCare, Inc.

Objective: To provide proper and consistent reimbursement; and to identify a service that is covered.

Procedure:

A. Cervical spine intervertebral disc prosthesis-surgical implantation of an FDA-approved cervical disc prosthesis at one level or two contiguous levels (CPT 22856, 22858) is reimbursable when ALL of the following criteria are met:

1. Imaging by CT, MRI or X-ray shows single or two contiguous level disc generation as a herniated nucleus polposus, spondylosis(osteophytes) or visible loss of disc height compared to adjacent levels.
2. The planned implant will be used in the reconstruction of a cervical disc at C3-C7, following single-level or two-level discectomy.
3. The individual is a candidate for single-level or two-level anterior cervical decompression and interbody fusion.(see medical policy on spine fusion)
4. EITHER of the following:
• Unremitting cervical radiculopathy and/or myelopathy (i.e. neck and arm pain) resulting in disability and/or neurological deficit that are refractory to at least six weeks of standard conservative non-operative management (may include reduced activities, analgesics, exercise, physical therapy) OR
• Demonstrated progressive signs/symptoms of nerve root and/or spinal cord compression despite nonoperative treatment prior to implantation that requires immediate/urgent surgical treatment.

B. Lumbar intervertebral disc prosthesis- surgical implantation of an FDA-approved lumbar disc prosthesis at a single level for degenerative disc disease (CPT 22857) is reimbursable when ALL of the following criteria are met:

1. Unremitting low back pain and significant functional impairment is refractory to at least six consecutive months of structured (with evidence of regularly scheduled follow-up appointments), physician supervised conservative medical management, which includes ALL of the following components-
   • Exercise, including core stabilization exercises
   • Nonsteroidal and/or steroidal medication (unless contraindicated)
   • Physical therapy, including passive and active treatment modalities
   • Activity and lifestyle modification

2. Single-level disc degeneration has been confirmed on imaging (i.e., computerized
tomography [CT] scan, magnetic resonance imaging [MRI]).

3. The implant will be inserted at an FDA approved lumbar/sacral level specific to the implant being used.

C. Revision of total disc arthroplasty (22861, 22862; 0165T) and removal of an implanted disc prosthesis (22864, 22865; 0164T) are reimbursable.

D. The following uses of cervical intervertebral disc prostheses are NOT reimbursable as they are considered experimental, investigational or unproven (not an all-inclusive list):

- Combined use of a prosthesis and spinal fusion (hybrid surgery)
- Implantation is planned at >2 diseased levels or two non-contiguous levels (CPT 0375T)
- There is prior fusion at an adjacent cervical level
- Prior surgery at the level to be treated
- Osteopenia, osteomalacia, or osteoporosis (e.g., T-score of -3.5, or -2.5, with associated compression fracture) is present
- Absence of neck or arm pain
- Rheumatoid arthritis or other autoimmune disease
- Paget’s disease, osteomalacia or any other metabolic bone disease
- Radiologic evidence of any of the following:
  - clinically significant cervical instability, such as kyphotic deformity or spondylolisthesis (e.g., > 3.5 mm subluxation or > 11 degrees angulation)
  - significant cervical anatomical deformity or compromised vertebral bodies at the index level (e.g.,
ankylosing spondylitis, rheumatoid arthritis, or compromise due to current or past trauma

- multilevel degenerative disc
- spinal metastases

E. The following uses of lumbar intervertebral disc prostheses are NOT reimbursable as they are considered experimental, investigational or unproven (not an all-inclusive list):

- Combined use of a prosthesis and spinal fusion (hybrid surgery)
- Simultaneous implantation at more than one lumbar level (CPT 0163T)
- The implant will be inserted outside of the recommended lumbar/sacral level for the specific implant being used.
- Osteopenia or osteoporosis (T-score < -1.0) is present.
- There is a prior lumbar fusion present
- Evidence on imaging of ANY of the following:
  - Degenerative spondylolisthesis of Grade 2 or greater
  - Multilevel degenerative disc disease
  - Nerve root compression or spinal stenosis
  - Pars interarticularis defect with either spondylolysis or isthmic spondylolisthesis
  - Scoliosis
  - Severe facet joint arthrosis
  - Spinal fracture
References


Bohlman HH. The ProDisc-C total disc replacement system was effective for symptomatic cervical disc disease. J Bone Joint Surg Am 2009; 91(11):2748 (Nov)


USFDA. FDA Approves Artificial Disc; Another Alternative to Treat Low Back Pain. FDA Talk Paper 2004; T04-45

USFDA. New Device Approval: Charite Artificial Disc – P040006. CDRH Consumer Information. October 26, 2004

Geisler FH, Blumenthal SL, Guyer RD, et al. Neurological complications of lumbar artificial disc replacement and comparison of clinical results with those related to lumbar arthrodesis in

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*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.