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


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