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Developed By: Medical Criteria Committee	

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Description:

When conservative treatment of degenerative disc disease is not effective, a spinal fusion and/or discectomy are commonly performed. A variety of prosthetic intervertebral discs have been investigated over the past few decades as an alternative to spinal fusion. Total disc replacement or spinal arthroplasty, is intended to maintain motion at the operative level once the damaged disc has been removed. The prosthetic disc is intended to restore or preserve the natural biomechanics of the intervertebral segment and to reduce further degeneration of adjacent levels.

Artificial intervertebral discs have been used internationally for many years. The first artificial disc to receive FDA approval in the United States was the SB Charite III lumbar disc. The Charite was approved on October 26, 2004. A second lumbar artificial disc, the ProDisc-L Total Disc Replacement, received FDA approval on August 14, 2006. The first artificial cervical disc to receive FDA approval is the Perestige Cervical Disc System which was approved on July 16, 2007. A second artificial cervical disc, the ProDisc-C Total Disc Replacement, received FDA approval on December 17, 2007. Examples of other prosthetic intervertebral discs are the Bryan cervical disc prosthesis, the Maverick artificial disc prosthesis, and the Flexicore disc. All of these are pending FDA approval.

Criteria - Lumbar:

- I. FDA-approved lumbar prosthetic intervertebral discs (e.g. Charite artificial disc, ProDisc-L Total Disc Replacement) will be covered to plan limitations when **ALL** of the following criteria are met:
 - a. The patient is skeletally mature; and
 - b. Diagnosis of degenerative disc disease at only one level (e.g. L4-5 or L5-S1 for Charite or L3-S1 for ProDisc-L) confirmed by patient history and radiographic studies; and
 - c. Disc replacement is planned for **one** level at L4-5 or L5-S1 for Charite or **one** level in the L3-S1 region for ProDisc-L; and
 - d. No more than Grade I spondylolisthesis at the involved level; and
 - e. Patient suffers from low back pain that has not responded to at least 6 months of conservative treatment; and
 - f. Patient is a candidate for spine surgery (such as a fusion); and
 - g. No prior lumbar spinal fusion

Contraindications - Lumbar:

Charite or ProDisc-L intervertebral disc prostheses will not be covered when any of the following conditions are present:

- Previous lumbar fusion
- Multiple levels of degenerative disc disease
- Osteoporosis or osteopenia
- Infection (active systemic or localized to the site of implantation)
- spinal tumor
- Lumbar spinal stenosis
- History of chronic steroid use
- Pregnancy
- Morbid obesity

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- Known allergy or sensitivity to implant materials (cobalt, chromium, molybdenum, polyethylene, titanium)

Criteria - Cervical

- I. FDA approved cervical prosthetic discs (e.g. Prestige Cervical Disc System or ProDisc-C Total Disc Replacement) will be covered to plan limitations with **ALL** of the following criteria are met:
 - a. The patient is 18 years of age or older and skeletally mature; and
 - b. Diagnosis of degenerative disc disease or disc herniation at only one level in the cervical spine between C3-C7; and
 - c. Patient suffers from neck pain of discogenic origin or radiculopathy that has not responded to at least 2 months of conservative treatment (time frame can be waived if the patient is experiencing progressive neurological worsening despite nonoperative treatment); and
 - d. No previous surgical intervention at the involved level or planned procedures at adjacent levels.

Contraindications - Cervical:

Prestige and ProDisc-C cervical discs will not be covered when any of the following conditions are present:

- More than one cervical level requiring surgical treatment
- Fused level adjacent to the level to be treated
- Evidence of cervical instability on dynamic flexion-extension radiographs, sagittal-plane translation of greater than 3.5mm, or sagittal-plane angulation of great than 20° at a single level
- Diagnosis of osteoporosis, osteopenia or osteomalacia
- Spinal metastases
- Severe facet joint disease at the involved level
- Active infection
- Known allergy or sensitivity to stainless steel, titanium or a titanium alloy
- Chronic steroid use
- Pregnant
- Morbid obesity

Limitations:

- Provider agrees to submit follow-up progress reports as requested by ODS on patients who have undergone artificial disc replacement.
- An ODS nurse will follow-up with the patient at 1 month, 3 months, 6 months and 1 year post-operatively to assess for complications, additional need for surgery, resolution of back problems, ability to return to work, etc. Progress reports may be requested from the surgeon's office as needed by the nurse.
- Authorization requests for surgery that involve intervertebral disc devices that are being studied in a clinical trial will be reviewed on a case-by-case basis. The intervertebral disc prosthesis itself that is being studied in the clinical trial is considered investigational and will not be covered by ODS. The cost of the artificial disc is usually paid for by the trial.

Information to be Submitted with Pre-Authorization Request:

1. Chart notes for the treating physician including radiographic studies and conservative treatment attempts
2. Institutional Review Board (IRB) approval from the requesting facility and signed informed consent by the member if the disc prosthesis is being studied in a clinical trial

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