mcmc
managing care. managing claims.
88 Black Falcon Avenue, Suite 353 Boston, MA 02210 (T) 800-227-1464 (F) 617-375-7777

DATE OF REVIEW:
08/13/2007

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE
Lumbar Charite artificial disc replacement L5-S1; Lumbar corset; cryo unit for ten day rental; one day length of stay; CPT 22857; L0627; E0249; and E0236.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION
Doctor of Osteopathy, Board Certified Anesthesiologist, Specializing in Pain Management

REVIEW OUTCOME
Upon independent review the reviewer finds that the previous adverse determination/adverse determinations should be: **Upheld**

Provide a description of the review outcome that clearly states whether or not medical necessity exists for each of the health care services in dispute.
The artificial disc, corset, cryo unit, and one day length of stay is not medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW
- MCMC: Case Report dated 07/25/07
- MCMC Referral dated 07/25/07
- DWC: Notice to MCMC, LLC of Case Assignment dated 07/25/07 from
- DWC: Confirmation of Receipt of a Request For a Review dated 07/18/07
- LHL009: Request For a Review By An Independent Review Organization dated 07/16/07
- Letters dated 07/11/07, 06/27/07 from CI Rep
- Surgery Pre-Authorization for Estimated Dates of Service 07/10 to 08/10/07
- Office notes dated 06/05/07, 04/24/07, 11/14/06 from, M.D.
- Surgery Pre-Op/Admission Orders dated 06/05/07
- M.D.: Letter dated 05/14/07
- Letters dated 04/24/07, 11/14/06 from, M.D.
- Center: Operative Reports dated 04/17/07, 02/26/07, 10/25/06, 10/18/06, 06/13/06 from, M.D.
- Chart notes (handwritten) dated 11/14/06
- Center: CT lumbar spine dated 10/25/06
- Center: Progress Report dated 09/18/06 from, M.D.
- Neurology: EMG/Nerve Conduction Study dated 09/18/06
- Orthopedic Report dated 07/26/06 from, M.D.
- Centers: Report of Medical Evaluation dated 06/08/06 from, M.D.
- Doctors: MRI lumbar spine dated 04/06/06
- Undated, handwritten doctor's note

88 Black Falcon Avenue, Suite 353 Boston, MA 02210 (T) 800-227-1464 (F) 617-375-7777

PATIENT CLINICAL HISTORY [SUMMARY]:
The injured individual is a male with date of injury xx/xx/xx. MRI showed normal morphology. The injured individual had two sacroiliac (SI) injections with no relief. He had a discogram that reported pain 5/10 at the L5 level with a negative CT post discogram. Electromyogram (EMG) has been negative. One neurosurgeon questioned the need for any surgical intervention based on the minimal to mild diagnostic findings. His partner suggested a disc replacement.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS AND CONCLUSIONS USED TO SUPPORT THE DECISION.
The injured individual had an MRI showing normal morphology at L5/S1 per his neurosurgeon, and he had a discogram that reported only mild pain reproduced at L5, not severe, concordant pain. The CT after discogram was negative. EMG was negative. The literature continues to indicate that artificial disc is an option versus fusion but randomized, multicenter long-term outcome studies are still lacking. In this case, clinically, the L5 disc does not appear to be involved to the extent that a surgical procedure of any kind is indicated.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES
Official Disability Guideline 2007: "Not recommended at this time for either degenerative disc disease or mechanical low back pain. See separate document with all studies focusing on Disc prosthesis. Studies have concluded that outcomes in patients with disc disease are similar to spinal fusion. (Cinotti-*Spine*, 1996) (Klara-*Spine*, 2002) (Zeegers, 1999) (Blumenthal, 2003) (Zigler, 2003) (McAfee, 2003) (Anderson-*Spine*, 2004) (Gamradt-*Spine*, 2005) (Gibson-*Cochrane*, 2005) A recent meta-analysis, published prior to the release of the Charite disc replacement prosthesis for use in the United States (on 6/2/2004 an FDA panel recommended approval of the Charite® disc from Johnson & Johnson DePuy), even concluded, "Total disc replacements should be considered experimental procedures and should only be used in strict clinical trials." (deKleuver, 2003) At the current time radiculopathy is an exclusion criteria for the FDA studies on lumbar disc replacement. (McAfee-*Spine*, 2004) Even though medical device manufacturers expect this to be a very large market (Viscogliosi, 2005), the role of total disc replacement in the lumbar spine remains unclear and predictions that total disc replacement (TDR) will replace fusion are premature. One recent study indicates that only a small percentage (5%) of the patients currently indicated for lumbar surgery has no contraindications to TDR. (Huang-*Spine*, 2004) Furthermore, despite FDA approval, the disc prosthesis is not generally covered by non workers' comp health plans (BlueCross BlueShield, 2004), or by some workers' comp jurisdictions. (Wang, 2004) Because of significantly varying outcomes, indications for disc replacement need to be defined precisely. In this study better functional outcome was obtained in younger patients under 40 years of age and patients with degenerative disc disease in association with disc herniation. Multilevel disc replacement had significantly higher complication rate and inferior outcome. (Siepe, 2006) With an implementation date of October 1, 2006, the Centers for Medicare & Medicaid Services (CMS), upon completion of a national coverage analysis (NCA) for Lumbar Artificial Disc Replacement (LADR), determined that LADR with the Charite lumbar artificial disc is not reasonable and necessary for Medicare patients. (CMS-coverage, 2006) (CMS-review, 2006) The U.S. Medicare insurance program said on May 28, 2007 in a draft proposal that it

88 Black Falcon Avenue, Suite 353 Boston, MA 02210 (T) 800-227-1464 (F) 617-375-7777

was rejecting coverage of artificial spinal disc replacement surgery no matter which disc was used. (CMS, 2007) This study reporting on the long-term results of one-level lumbar arthroplasty reported that after a minimum 10-year follow-up, 90% of patients had returned to work, including 78% of patients with hard labor level employment returning to the same level of work. (David, 2007) According to this prospective, randomized, multicenter FDA IDE study, the ProDisc-L has been shown to be superior to circumferential fusion by multiple clinical criteria. (Zigler, 2007) While disc replacement as a strategy for treating degenerative disc disease has gained substantial attention, it is not currently possible to draw any conclusions concerning disc replacement's effect on improving patient outcomes. The studies quoted above have failed to demonstrate a superiority of disc replacement over simple fusion for the limited indications for surgical treatment of lower back pain. Thus disc replacement is considered a controversial and unproven alternative to fusion surgery. Note: On August 14, 2006, the FDA approved the ProDisc® Total Disc Replacement by Synthes Spine, Inc."