blue of california **Medical Policy**	**Effective Date: April 05, 2007**	
Covered: No **Type: IE**	**Section: Surgery**	**Code:0090T - 0098T, 22526, 22527, 22857, 22862, 22865, 0163T, 0164T, 0165T, 0090T and 0092T, No Specific Code for Cervical**

The materials provided to you are guidelines used by this plan to authorize, modify, or deny care for persons with similar illness or conditions. Specific care and treatment may vary depending on individual need and the benefits covered under your contract. These policies are subject to change as new information becomes available.

Subject:	**Artificial Intervertebral Disc: Lumbar and Cervical Spine**
Description	When conservative treatment of degenerative disc disease fails, a common surgical approach is spinal fusion; over 200,000 spinal fusions are performed each year. However, the outcomes of spinal fusion have been controversial over the years, in part due to the difficulty in determining if a patient's back pain is related to degenerative disc disease and in part due to the success of the procedure itself. In addition, spinal fusion alters the biomechanics of the back, potentially leading to premature disc degeneration at adjacent levels, a particular concern for younger patients. During the past 30 years, a variety of artificial intervertebral discs have been investigated as an alternative approach to fusion. This approach, also referred to as total disc replacement or spinal arthroplasty, is intended to maintain motion at the operative level once the damaged disc has been removed and to maintain the normal biomechanics of the adjacent vertebrae. While artificial intervertebral discs have been used internationally for over 10 years, only 2 devices have received approval from the U.S. Food and Drug Administration (FDA). The CHARITÉ® and PRODISC®-L devices have received approval. Other devices are currently under investigation in this country as part of the FDA process of approval, including the FlexiCore and Maverick devices. The study protocol for the CHARITÉ device consisted of a randomized clinical trial comparing the artificial intervertebral disc to a spinal fusion using a threaded fusion cage with autologous bone graft. Patients were randomized in a 2:1 fashion, with 205 receiving the artificial disc and 99 undergoing the fusion procedure. The study completed accrual in 2001, with a 24-month follow-up. The PRODISC trial is not yet published, but

	some results are available from FDA documents. The FlexiCore and Maverick devices are undergoing investigation in similarly designed randomized trials. Potential candidates for artificial disc replacement have chronic low back pain attributed to degenerative disc disease, lack of improvement with non-operative treatment, and none of the contraindications for the procedure, which include multilevel disease, spinal stenosis or spondylolisthesis, scoliosis, previous major spine surgery, neurologic symptoms, and other minor contraindications. These contraindications make artificial disc replacement suitable for a subset of patients in which fusion is indicated. Patients who require procedures in addition to fusion such as laminectomy and/or decompression are not candidates for the artificial disc.
Medical Policy	Artificial intervertebral discs are considered **investigational** for treatment of disorders of the cervical spine, including degenerative disc disease. Artificial intervertebral discs of the lumbar spine are considered **investigational**.
Source:	▪ FDA Approved Prodisc, August 2006 ▪ BSC California Technology Assessment Forum (CTAF), October 2005: Artificial Disc Replacement for Degenerative Disc Disease of the Lumbar Spine. Full review refer to www.ctaf.org ▪ BCBSA MPP #7.01.17. Artificial Intervertebral Disc. ▪ Blue Cross Blue Shield Association TEC Assessment 2005. Vol. 20. No. 1. Artificial Vertebral Disc Replacement. Full review refer to www.bcbs.com ▪ BSC California Technology Assessment Forum (CTAF), February 2005: Artificial Disc Replacement for Degenerative Disc Disease of the Lumbar Spine. Full review refer to www.ctaf.org ▪ Centers for Medicare and Medicaid Services (CMS). Proposed decision memo for lumbar artificial disc replacement (CAG-00292N) ▪ BCBSA MPP 4:2006 Artificial Intervertebral Disc: Cervical Spine ▪ Centers for Medicare and Medicaid Services (CMS). Final decision memo for lumbar artificial disc replacement.

Policy History	Date	Activity
Medical Policy Committee	03/01/2005	MPC adoption CTAF Technology

		Assessment February 2005. New Policy
Administrative Review/Update	06/01/2005	Administrative review: BCBSA TEC Vol. 20. No. 1 and MPP#7.01.17 Statements concur and unchanged
Medical Policy Committee	12/01/2005	CTAF review Oct. 2005 against recommendation; MPC adopted review/recommendation. Policy statement unchanged as investigational
Administrative Update: ProDisc	09/01/2006	Update noting Pro Disc received FDA clearance
Medical Policy Committee	12/07/2006	Update policy. Include cervical spine adopted from BCBSA MPP.
Medical Policy Committee	04/05/2007	Reviewed New Literature on Artificial Disc - Lumbar Spine. Policy Statement Unchanged