

Corporate Medical Policy

Artificial Intervertebral Disc

File Name: artificial_intervertebral_disc
Policy Number: SUR6042
Origination: 4/2004
Last Review: 5/2008
Next Review: 5/2010

Description of Procedure or Service

When conservative treatment of [degenerative](#) disc disease fails, a common surgical approach is [spinal fusion](#); over 200,000 [spinal fusion](#)s are performed each year. However, the outcomes of [spinal fusion](#) have been controversial over the years, in part due to the difficulty in determining whether the 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 normal function of the back, potentially leading to premature disc degeneration at neighboring levels, a particular concern for younger patients. A variety of artificial [intervertebral](#) discs have been investigated over the past 50 years as an alternative 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 function of the next vertebrae.

While artificial [intervertebral](#) discs have been used internationally for over 10 years, a variety of devices are currently under investigation in this country as part of the U.S. Food and Drug Administration (FDA) process of approval. The Charite intervertebral disc developed by DePuy Sine, Inc. was approved by the FDA in October of 2004. The FDA approval is for use in patients who have degenerative disc disease at one level in the lumbar spine that have not been able to obtain relief from low back pain for a period of at least 6 months. The Charite disc has a plastic central free component and two metal endplates that fit into neighboring vertebrae. The disc is implanted after the damaged disc has been surgically removed. The central component is held into place by the surrounding normal soft tissues and shifts within the disc space during spinal motion. These devices are designed to restore disc height and normal physiologic motion. DePuy Spine is required by the FDA to conduct post-approval studies to assess long-term safety and efficacy of the disc. The FDA is also interested in the effect of the prosthetic disc on adjacent spinal structures. The Pro-Disc and Maverick devices are also artificial lumbar discs that are currently under investigation in the United States as part of the FDA-approval process. The Bryan Cervical Disc System is an artificial disc specifically designed for the cervical spine. This device is also currently under investigation under the FDA IDE (Investigational Device Exemption) process.

Policy

BCBSNC will not provide coverage for Artificial Intervertebral Disc because they are considered investigational. BCBSNC does not cover investigational services.

Benefits Application

Please refer to Certificate for availability of benefits. This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design, therefore certificate language should be reviewed before applying the terms of the policy.

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When Artificial Intervertebral Disc is covered

Not applicable.

When Artificial Intervertebral Disc is not covered

BCBSNC will not provide coverage for Artificial [Intervertebral](#) Disc because they are considered investigational. BCBSNC does not cover investigational services.

Policy Guidelines

A 2008 literature search of various technology evaluation services indicates that there is insufficient data regarding the long-term durability of the prosthetic disc or the impact of complications related to this technology. Information acquired from experience with other prosthetic implants such as artificial knee joints indicate that over time metal-on-metal and metal-on-polyethylene can have adverse effects on the surrounding spinal structure or tissue. There are several multicenter randomized controlled trials being conducted currently in the US to compare the safety and effectiveness of artificial intervertebral disc to spinal fusion for those patients with degenerative disc disease. This evolving technology shows much promise but the need for long-term outcomes beyond 2-3 years are important to answer these questions.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 0092T, 0095T, 0098T, 0163T, 0164T, 0165T, 22856, 22857, 22861, 22862, 22864, 22865.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Policy Key Words

Key Words: Artificial Intervertebral Disc, Spinal Arthroplasty, Total Disc Replacement, SB Charite III, Pro-Disc, Maverick, Bryan Cervical Disc, SUR6042.

Medical Term Definitions

Arthroplasty

surgical repair of a joint.

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Degenerative

a progressive deterioration.

Intervertebral

located between two discs that are in contact with each other.

Spinal fusion

a procedure that involves fusing together two or more vertebrae in the spine using either bone grafts or metal rods.

Scientific Background and Reference Sources

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.87, 4/29/03.

Specialty Matched Consultant Advisory Panel - 6/2004

ECRI's Health Technology Forecast. (2004, October). FDA approves first artificial disc to treat low back pain. Retrieved 12/28/04 from http://www.ta.ecri.org/Forecast/Prod/summary/detail.aspx?doc_id==5516&q=artificial+intervertebral&anm=WynneB

ECRI TARGET Database Report #852. (2004, December). Artificial intervertebral disc replacement for degenerative disc disease. Retrieved on 12/28/04 from http://www.target.ecri.org/summary/detail.aspx?doc_id+4927&q=artificial+intervertebral&anm=WynneB

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BCBSA Technology Evaluation Center. (2005, April). Artificial vertebral disc replacement. Retrieved 5/13/2005 from http://www.bcbsa.com/tec/vol20/20_01.html

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.87, 4/1/2005

Institute for Clinical Systems Improvement, (2005, December). Technology assessment report: Lumbar artificial intervertebral disc. TA #92. Retrieved 2/24/2006, from <http://www.icsi.org/knowledge/detail.asp?catID=107&itemID=2372>.

Specialty Matched Consultant Advisory Panel - 5/2006

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.87, 1/10/2008

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.108, 12/13/2007

Specialty Matched Consultant Advisory Panel - 5/2008

Policy Implementation/Update Information

7/29/04 New policy implemented. Artificial Intervertebral Disc is considered investigational. Reviewed by Specialty Matched Consultant Advisory Panel 6/22/04. Notification given 7/29/04. Effective date 10/14/04.

1/20/05 Removed the statement from the Description of Service or Procedure section that indicated; "No artificial intervertebral disc has received FDA approval as of May 2004." Added information related to the approval by FDA of the Charite disc in October of 2004. Rationale added to Policy Guidelines section. References added.

6/2/05 References added. Policy number added to Key Words section.

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- 6/16/05 Date added to reference.
- 7/7/05 Added new CPT codes: 0090T, 0091T, 0092T, 0093T, 0094T, 0095T, 0096T, 0097T, 0098T
- 1/19/06 Added new 2005 CPT code 0091T to "Billing/Coding" section.
- 6/5/06 Specialty Matched Consultant Advisory Panel review 5/3/2006. No changes to policy statement. Updated date of literature search in "Policy Guidelines" section. References added.
- 1/3/07 Added the following new 2007 CPT codes: 0163T, 0164T, 0165T, 22857, 22862, and 22865 from "Billing/Coding" section. Removed deleted CPT codes, 0091T, 0094T, and 0097T.
- 6/30/08 Specialty Matched Consultant Advisory Panel review 5/29/08. No changes to policy statement. References added.
- 1/5/09 Added CPT codes 22856, 22861, and 22864 to the "Billing/Coding" section. Removed deleted CPT codes 0090T, 0093T, and 0096T.

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.