ARTIFICIAL DISC AND DISC NUCLEUS REPLACEMENT

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.
ARTIFICIAL DISC AND DISC NUCLEUS REPLACEMENT (cont.)

Description:

Artificial Disc Replacement:
Artificial disc replacement has been investigated as a technique to restore disc height and normal physiologic motion. The procedure utilizes an intervertebral disc prosthesis to replace a degenerated or diseased disc. Devices use 2 metal endplates that are fitted into adjacent vertebrae and a central free component. This central component is held in place by the surrounding normal soft tissues (such as ligaments and the disc annulus) and shifts within the disc space during spinal motion.

Artificial disc devices with FDA approval:

- Bryan® Cervical Disc Prosthesis
- Charité Artificial Disc
- IN MOTION®
- Prestige® Cervical Disc System
- ProDisc™-C Total Disc Replacement
- ProDisc®-L Total Disc Replacement Device

Artificial disc devices currently under clinical trial include, but are not limited to:

- Kineflex Spinal System
- Kineflex-C Spinal System
- Maverick™ Artificial Disc
- Prodisc® Total Disc Replacement

Disc Nucleus Replacement:
Involves removing the disc nucleus and replacing it with arthroplasty devices while preserving the annulus and endplates. This is a minimally-invasive, disc height and motion preserving approach that has been investigated as a technique to treat lower back pain associated with degenerative disc disease. The Dascor® Disc Arthroplasty system is one system that has been investigated for this purpose. It consists of a two-part curable polyurethane and expandable polyurethane balloon.
ARTIFICIAL DISC AND DISC NUCLEUS REPLACEMENT (cont.)

Criteria:

Lumbar Spine:

- Artificial disc replacement* of the lumbar spine is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Cervical Spine:

- Artificial disc replacement* of the cervical spine is considered experimental or investigational based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

  * Artificial disc replacement does not include fusion cage, dowel or support structure.

Disc Nucleus Replacement:

- Disc nucleus replacement using the following devices is considered experimental or investigational based upon:
  1. Lack of final approval from the Food and Drug Administration, and
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  3. Insufficient evidence to support improvement of the net health outcome, and
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  5. Insufficient evidence to support improvement outside the investigational setting.

These devices include, but are not limited to:

- Dascor Disc Arthroplasty System
ARTIFICIAL DISC AND DISC NUCLEUS REPLACEMENT (cont.)

Resources:

Resources published prior to 2006 may be requested from the BCBSAZ Medical Policy and Technology Research Department.


8. BCBS Association Technology Assessment Program. Artificial Lumbar Disc Replacement. June 2007;22(2).


ARTIFICIAL DISC AND DISC NUCLEUS REPLACEMENT (cont.)

Resources: (cont.)


ARTIFICIAL DISC AND DISC NUCLEUS REPLACEMENT (cont.)

Resources: (cont.)


ARTIFICIAL DISC AND DISC NUCLEUS REPLACEMENT (cont.)

Resources: (cont.)


40. TEC Clearinghouse News. Five-Year Results of the ProDisc-L (Artificial Intervertebral Lumbar Disc) Trial. 03/30/2012.


ARTIFICIAL DISC AND DISC NUCLEUS REPLACEMENT (cont.)

Resources: (cont.)


FDA Premarket Approval Database for ProDisc®-L Total Disc Replacement Device (Synthes Spine):

- FDA-approved indication: For spinal arthroplasty in skeletally mature patients with degenerative disc disease (ddd) at one level from L3-S1 and who have failed at least six months of conservative treatment prior to implantation of the Prodisc-L total disc replacement.

FDA Premarket Approval Database for Bryan Cervical Disc Prosthesis:

- FDA-approved indication: In skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. The Bryan device is implanted via an open anterior approach. Intractable radiculopathy and/or myelopathy is defined as any combination of the following: disc herniation with radiculopathy, spondylotic radiculopathy, disc herniation with myelopathy, or spondylotic myelopathy resulting in impaired function and at least one clinical neurological sign associated with the cervical level to be treated, and necessitating surgery as demonstrated using computed tomography (CT), myelography and CT, and/or magnetic resonance imaging (MRI). Patients receiving the Bryan Cervical Disc should have failed at least six weeks of non-operative treatment prior to implantation of the Bryan Cervical Disc.
ARTIFICIAL DISC AND DISC NUCLEUS REPLACEMENT (cont.)

Resources: (cont.)

FDA Premarket Approval Database for Prestige® Cervical Disc System:

- FDA-approved indication: In skeletally mature patients for reconstruction of the disc from C3-C7 following single-level discectomy for intractable radiculopathy and/or myelopathy. Intractable radiculopathy and/or myelopathy should present with at least one of the following items producing symptomatic nerve root and/or spinal cord compression which is documented by patient history (e.g., pain [neck and/or arm pain], functional deficit, and/or neurological deficit), and radiographic studies (e.g., CT, MRI, x-rays, etc.): 1) herniated disc, and/or 2) osteophyte formation.

FDA Premarket Approval Database for In Motion Artificial Disc (DePuy Spine):

- FDA-approved indication: For spinal arthroplasty in skeletally mature patients with degenerative disc disease (DDD) at one level from L4-S1. DDD is defined as discogenic back pain associated with degeneration of the disc confirmed by patient history and radiographic studies. The appropriate patients should have no more than 3mm of spondylolisthesis at the involved level without spondyloysis. Appropriate patients should have failed at least six months of conservative treatment prior to implantation of the In Motion Lumbar Artificial Disc.