BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 10/29/13
LAST REVIEW DATE:
LAST CRITERIA REVISION DATE:
ARCHIVE DATE:

ARTIFICIAL INTERVERTEBRAL DISC OF THE LUMBAR SPINE

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.

Description:

Artificial intervertebral disc replacement for the lumbar spine is proposed as an alternative to fusion in individuals with chronic low back pain related to degenerative disc disease (DDD).

Artificial lumbar disc devices with FDA approval:

- Charité® Artificial Disc
- IN MOTION® Lumbar Artificial Disc
- ProDisc®-L Total Disc Replacement Device

Artificial lumbar disc devices currently under investigation include, *but are not limited to*:

- Activ-L™
- FlexiCore™
- Maverick™ Artificial Disc

ARTIFICIAL INTERVERTEBRAL DISC OF THE LUMBAR SPINE (cont.)

Description: (cont.)

Disc nucleus replacement devices, also known as prosthetic disc nucleus (PDN) devices, have also been investigated for the treatment of degenerative disc disease (DDD). The Dascor® Disc Arthroplasty system has been investigated for treatment of DDD of the lumbar spine.

Criteria:

- 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.

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

- 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 INTERVERTEBRAL DISC OF THE LUMBAR SPINE (cont.)

Resources:

Resources prior to 10/29/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 7.01.87 BCBS Association Medical Policy Reference Manual. Artificial Intervertebral Disc: Lumbar Spine. Re-issue date 09/13/2012, issue date 04/29/2003.