BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 08/21/13
LAST REVIEW DATE: 08/19/14
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ANNULAR REPAIR

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:

Annular Repair:
The annulus fibrosus is a ring of fibrocartilage and fibrous tissue around the intervertebral disc, surrounding the nucleus pulposus of the spine. During a surgical discectomy or some other spine surgeries, an open pathway or hole (defect) is made in the annulus fibrosus, which is then left to heal. The defect is thought to contribute to recurrent disc herniation and a higher rate of reoperations; surgeons are beginning to repair the defect at the time of the initial procedure. Annular tissue repair systems have been investigated as methods to repair these annular defects.

The Xclose Tissue Repair System™ has been investigated as a method of soft tissue re-approximation of the annulus fibrosus after a lumbar discectomy procedure. It is used to repair the defect at the time of the initial procedure. Sutures are placed to re-approximate the annular tissue and seal the defect. The Xclose Tissue Repair System is currently under clinical trial. Anulex Technologies, Inc., is the product developer.

ANNULAR REPAIR (cont.)

Description: (cont.)

The Inclose Surgical Mesh System™ is a mesh braided implant used to provide a barrier and scaffold for soft tissue repair. It has been investigated as a technique to repair annular defects made during spine surgery. It is inserted into the hole (defect) and expanded thereby "plugging" the hole. Anulex Technologies, Inc., manufactures the Inclose Surgical Mesh System.

Criteria:

- Annular repair using the following annular tissue repair systems 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, and
  4. Insufficient evidence to support improvement outside the investigational setting.

  Annular tissue repair systems include, *but are not limited to*:

  - Inclose Surgical Mesh System
  - Xclose Tissue Repair System

Resources:

1. Bailey A, Araghi A, Blumenthal S, Huffmon GV. Prospective, Multicenter, Randomized, Controlled Study of Anular Repair in Lumbar Discectomy: Two-Year Follow-up. *Spine (Phila Pa 1976).* Jun 15 2013;38(14):1161-1169.

2. Parker SL, Grahovac G, Vukas D, Ledic D, Vilendecic M, McGirt MJ. Cost savings associated with prevention of recurrent lumbar disc herniation with a novel annular closure device: a multicenter prospective cohort study. *J Neurol Surg A Cent Eur Neurosurg.* Sep 2013;74(5):285-289.