Policy Name: Annulus Fibrosus Repair Devices
Effective Date: 1/21/2019

Important Information – Please Read Before Using This Policy

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica coverage policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica coverage policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

Coverage Policy

Surgical devices for annulus fibrosus repair following spinal surgery are investigative and unproven, and therefore NOT COVERED. There is insufficient reliable evidence in the form of high quality peer-reviewed medical literature to establish the safety and efficacy or effects on health care outcomes.

Note: This policy is no longer scheduled for routine review of the scientific literature.

Description

In a healthy intervertebral disc, the annulus fibrosis (the fibrous ring surrounding the disc) firmly encloses the nucleus pulposus (the jelly-like substance at the center of the disc). However, degenerative changes arising from loss of hydration of the nucleus pulposus may lead to tears within the annulus fibrosus, causing the ingrowth of blood vessels and activation of pain receptors within the annulus resulting in chronic discogenic pain.

An annular repair/closure device has been purported for treatment following a spinal decompression (discectomy) surgery. It has been suggested that annular closure may reduce the risk of disc reherniation and the need for a fusion. The Xclose Tissue Repair System and the Inclose Surgical Mesh System are two examples of devices being investigated as methods of soft tissue repair of the annulus fibrosus after a lumbar discectomy procedure.

FDA Approval

Both the Xclose™ Tissue Repair System and the Anchor Band Suturing System, (Anulex Technologies, Inc., Minnetonka, MN) received initial FDA marketing approvals in 2006.

The Inclose Surgical Mesh System (Anulex Technologies, Inc., Minnetonka, MN), received initial FDA marketing approval in 2005.

The Disc Annular Repair Technology (DART) System (Magellan Spine Technologies, Inc., Irvine, CA) received European CE Mark approval in 2009. The DART system has not currently received FDA marketing clearance in the United States.

Prior Authorization

Prior authorization is not applicable. Claims for this service are subject to retrospective review and denial of coverage, as investigative services are not eligible for reimbursement.
Coding Considerations
Use the current applicable CPT/HCPCS code(s). The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.

CPT Codes
64999 - unlisted procedure, nervous system

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Re-Review Date(s): 11/18/2015
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2/10/2020 – administrative update; formatting

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