Healthy Blue

Medical Policy

Subject:	Annulus Closure After Discectomy		
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Description/Scope

This document addresses annulus closure devices proposed for use in annular repair following a discectomy procedure.

Position Statement

Investigational and Not Medically Necessary:

Annulus closure using devices for annular repair is considered **investigational and not medically necessary.**

Rationale

The intervertebral disc is composed of two distinct structures: the nucleus pulposus and surrounding annulus fibrosus. Treatment of a herniated disc may involve removal (discectomy) of the herniated nucleus pulposus material through an annular incision (annulotomy), or in some cases, repair of an annular defect responsible for the herniation. The annulus fibrosus has a limited healing capacity after an annulotomy and reherniation may result in a poor clinical outcome. A variety of surgical techniques designed to preserve, repair, or reinforce the annulus fibrosus following annulotomy are under study. The following devices are proposed for use in annulus closure after a discectomy to reduce the risk of reherniation.

Xclose® Tissue Repair System

The Xclose Tissue Repair System (Anulex Technologies, Inc., Minnetonka, MN) received U.S. Food and Drug Administration (FDA) 510(k) clearance on August 7, 2006. The FDA labeled indications state the system is used for soft tissue approximation in general and orthopedic surgery procedures. The Xclose Tissue Repair System (modified sutures with anchors) was subsequently proposed for re-approximation of the annulus fibrosus after a lumbar discectomy procedure. In February 2011, the FDA required the manufacturer submit a premarket approval application supported by clinical data from an investigational device exemption (IDE) study for this application. The FDA considered the annulus fibrosus repair indication as described in a clinical trial that evaluated use of the device for repair of the annulus fibrosus after discectomy to be investigational and outside the scope of Anulex Technologies, Inc. 510(k) clearance for the Xclose Tissue Repair System. Anulex Technologies, Inc. subsequently submitted an application to the FDA to obtain approval for increased specificity to the label indication for the Xclose Tissue Repair System that would include the specific anatomy and additional claims defined within the

published study. Bailey and colleagues (2013) reported the study results in a prospective, multicenter, single-blind, randomized, controlled clinical trial of individuals who: 1) were candidates for a 1- or 2-level discectomy procedure; 2) were experiencing persistent and uncontrolled leg pain greater than "4" on a 10-point visual analogue scale (VAS); 3) had radiographic evidence of intervertebral disc herniation corresponding to symptoms; and 4) were unresponsive to nonoperative care including 6 consecutive weeks of therapy. The primary efficacy outcome measure was rate of reoperation for recurrent herniation. Secondary outcomes were VAS for leg and back pain, Oswestry Disability Index (ODI), and Short Form-12 (SF-12) Health Survey scores.

After completion of a standard discectomy (n=750) and evaluation of the annulus by the treating surgeon to assess its adequacy for reapproximation (if deemed sufficient), the remaining participants (n=728) were randomized in a 2:1 ratio to annular repair with the Xclose Tissue Repair System (n=478) or no annular repair (n=250, control group). Self-reported functional outcome measures assessed leg pain (both worst affected leg and contralateral leg) based on the 10-point VAS score, ODI, and SF-12 Health Survey at baseline and 2-week, 6-month, 1-year, and 2-year postoperative visits. Serious adverse events resulting in medical or surgical intervention, required hospitalization, or prolongation of existing hospitalization were similar between groups, with the most notable being symptoms of back and leg pain in 34 of 478 (7.1%) participants in the Xclose group and 18 of 249 (7.2%) participants in the control group (p=0.9541). VAS leg and back pain, ODI, and SF-12 outcomes demonstrated statistically significant improvement for both groups from preoperative baseline values; however, there was no statistically significant difference between the groups at any of the follow-up points indicating durability of the results over time (p>0.05).

The primary outcome measure, reherniation surgery rates at 3 months, 6 months, and 2 years, did not differ statistically between the experimental and control groups. However, a post hoc subgroup analysis was conducted for individuals presenting with predominant leg pain as indicated by VAS leg and back pain scores (n=209 Xclose group; n=105 control group). For this subgroup, the frequency of reoperation due to reherniation was reported as lower in the Xclose group at 3-month follow-up (1.0% vs. 5.9%; p=0.019) and 6-month follow-up (2.0% vs. 6.9%; p=0.046). However, this difference between the 2 groups in reoperation for disc reherniation was not seen at 2 years (6.7% vs 12.1%; p=0.134). Limitations of this study include the use of a post hoc analysis, the lack of consecutive enrollment of participants at each site because certain individuals did not meet the inclusion/exclusion criteria and declined to participate in the randomized study, and the declining numbers of participants who were available at the 2-year follow-up for inclusion in the analysis (X-close, 85.8%; control group, 87.3%; p=0.599). Additional randomized controlled studies with participants reporting statistically significant improvement in clinical outcomes and a decrease in overall complication rates are needed to determine the long-term safety and efficacy of the Xclose Tissue Repair System in reducing the need for subsequent reherniation surgery after post-discectomy annular repair.

Inclose™ Surgical Mesh System

The Inclose Surgical Mesh System (Anulex Technologies, Inc., Minnetonka, MN) received FDA 510(k) clearance on August 18, 2005 and is proposed as an alternative procedure for annular repair following discectomy to re-approximate the compromised tissue of the annulus fibrosus. The device is comprised of a mesh implant and two suture assemblies referred to as anchor bands. The surgical mesh implant is comprised of polyethylene

terephthalate (PET) monofilament expandable braided material that is preloaded on a disposable delivery tool inserted through the aperture of the tissue defect and affixed to surrounding soft tissue with the anchor bands. To date, no evidence was found in the peer-reviewed medical literature evaluating the efficacy and safety of the Inclose Surgical Mesh System for any indication.

Barricaid® Anular Closure Device (ACD)

The Barricaid ACD (Intrinsic Therapeutics, Inc., Woburn, MA) was granted FDA premarket approval on February 8, 2019 and is indicated for:

> reducing the incidence of reherniation and reoperation in skeletally mature patients with radiculopathy (with or without back pain) attributed to a posterior or posterolateral herniation, and confirmed by history, physical examination and imaging studies which demonstrate neural compression using MRI to treat a large anular defect (between 4-6 mm tall and between 6-10 mm wide) following a primary discectomy procedure (excision of herniated intervertebral disc) at a single level between L4 and S1 (U.S. Food and Drug Administration, 2019).

Implanted between the annulus and the nucleus, the Barricaid ACD forms a strong, yet flexible wall that creates a mechanical barrier that closes the annular defect.

Trummer and colleagues (2013) compared the results of three prospective, multicenter, single-arm studies performed in Europe that investigated whether implantation with the Barricaid ACD during discectomy reduced the rate of facet degeneration. A total of 75 participants were enrolled in two studies using the Barricaid ACD (discectomy-Barricaid). The third study included 137 discectomy-only participants as the Barricaid ACD was not clinically available at the time. Prior to surgery, participants in all three studies had confirmed primary lumbar disc herniation, failed at least 6 weeks of conservative treatment, and had VAS ipsilateral-leg pain of at least 40 out of 100. Preoperatively, only the discectomy-Barricaid participants were required to have an ODI $\geq$ 40 and maximum defects that were $\leq$ 60 millimeters (mm) tall by 10 mm wide. A single independent radiologist compared preoperative and 12-month postoperative computed tomography (CT) scan interpretations for the evaluable 94 discectomy-only and 63 discectomy-Barricaid participants. When grouping grades 0 and grades I versus grades II and III, there was no difference in the preoperative distribution of facet degeneration in the discectomy-only and discectomy-Barricaid participants (p=1.000). At 12 months postoperative, the discectomy-only participants had a significantly higher grade of facet degeneration when compared to the discectomy-Barricaid participants, reported as 22% versus 38% grade 0, 62% versus 55% grade I, 15% versus 5% grade II, and 1% versus 2% grade III, respectively (p=0.015). Univariate logistic regression analysis performed for all participants suggested a lower probability for facet degeneration was significantly correlated with smaller annular defects (p=0.041) and discs implanted with the Barricaid (p=0.014). A trend was noted toward decreased facet degeneration for discs with less nuclear material removed during discectomy (p=0.079) and discs with larger preoperative disc heights (p=0.080). The results, however, failed to show statistically significant correlations in any of the three clinical outcome scores (ODI, VAS-Back and VAS-ipsilateral-leg pain scores). Limitations of this study include use of a single radiologist not blinded to the treatment and control groups at follow-up since the Barricaid ACD is visible on CT, the 2 study

groups were not subjected to the same preoperative inclusion criteria (preoperative ODI and defect size), and the short-term follow-up of 12 months.

Parker and colleagues (2013) prospectively compared the 12-month incidence of same-level recurrent disc herniation, disc height loss, and cost outcomes in a nonrandomized study of 46 European subjects undergoing lumbar discectomy for a single-level herniated disc to a second consecutive cohort of 30 subjects undergoing 31 lumbar discectomy procedure with implantation of the Barricaid ACD. Additional post hoc analysis modeled on direct Medicare costs and indirect costs of work-day losses was performed to predict cost savings between the procedures associated with surgical treatment of same-level, recurrent lumbar disc herniation. The authors reported a reduction in recurrent disc herniation from 6.5 % to 0% was associated with the annular closure device within the 12-month follow-up period, although the study was underpowered to observe statistical significance. Limitations of this study include the post hoc manner of the analysis and lack of other data reporting associated morbidity and complications following discectomy, such as measurements of back pain severity.

In 2017, Kuršumović and Rath published a retrospective analysis to assess the Barricaid ACD in subjects undergoing discectomy for lumbar disc herniation. Subjects (n=171) were assessed preoperatively, 3 months postoperatively, and 12 months postoperatively through ODI and VAS scores, and plain radiographs and functional imaging (MRI or CT at preoperative visit and 12 month visit). The authors found symptomatic reherniation in 6 subjects (3.5%), partially or completely detached mesh from the titanium anchor in 12 subjects (8.8%), and all subjects improved in ODI and VAS scores by the 12 month follow-up (ODI: 15.8 ± 16.9; VAS Leg: 23.3 ± 27.1; VAS Back: 26.9 ± 24.8). Study limitations include retrospective design, lack of comparator group, minimal exclusion criteria, small sample size, and short follow-up.

Thomé and colleagues (2018) reported on a multicenter, randomized clinical trial that evaluated whether the Barricaid ACD in adjunct to lumbar microdiscectomy would decrease reherniation and reoperation rates compared to lumbar microdiscectomy alone. Individuals were randomly assigned to the ACD group (n=267) or the control group (n=283). Clinical follow-up at 2 years (91% compliance) showed symptomatic reherniation at 12% for the ACD group and 25% for the control group ($p<0.001$), and reoperation at 5% for the ACD group and 13% for the control group ($p=0.001$). End plate changes were 84% in the ACD group versus 30% in the control group ($p<0.001$), and ODI scores were comparable between the two groups. A limitation to this study is possible bias due to lack of blinding.

The results of a prospective, single-center study of lumbar discectomy for sciatica caused by intervertebral disc herniation with adjunctive ACD implantation to reduce herniation recurrence risk among high-risk individuals with large annular defects were released in 2019 by Ardeshiri and colleagues. Following operation at 6 weeks, 12 weeks, 26 weeks, 1 year, and 2 years, 75 individuals were evaluated for reoperation, herniation recurrence, back pain and leg pain severity (each measured on a 100 mm visual analog scale), and ODI. Individual follow-up compliance was 91% (n=68) at 3 months, 92% (n=69) at 6 months, 96% (n=72) at 1 year, and 90% (n=67) at 2 years. Compliance was not reported for the 6-week follow-up. The evaluators reported outcomes cumulatively through 2 years. Results showed the event incidence was 4.0% for reoperation and 1.4% for herniation recurrence with mean leg pain severity decreasing from 73 to 6 ($p<0.001$), back pain severity decreasing from 51 to 13 ($p<0.001$), and ODI decreasing from 49 to 7 ($p<0.001$). Adverse events included 1 individual with a dural tear and another individual

with the ACD improperly implanted. Limitations to this study included no control group with randomization, reporting cumulative results, the study being conducted at a single center, and lack of radiographic assessments of possible vertebral endplate changes, disc height changes, and device complications.

The Barricaid ACD is being studied in an ongoing prospective, single-arm, multicenter study to confirm the efficacy of the device when used as adjunct to a primary lumbar limited discectomy, to limited discectomy alone, with regard to preventing reherniation and the recurrence of pain or dysfunction in a US population. The study estimated enrollment is 75 participants and each participant will be followed for at least 12 months. The estimated study completion date is December 2021.

Disc Annular Repair Technology (DART) System

The DART System (Magellan Spine Technologies, Inc., Irvine, CA) is a polyetheretherketone (PEEK) implant that provides closure of the annulus following a standard lumbar microdiscectomy procedure. When implanted, the DART is placed near the central axis of rotation along the posterior edge of the vertebral body. The device is aligned with the vertebral body load column, the strongest of the three primary spinal vertical load columns and is secured in place at the apophyseal ring, the densest bone of the vertebral body. There are no studies currently published in the peer-reviewed medical literature to support the efficacy and safety of the DART system, or that it will improve health outcomes for use in individuals for any indication.

In April 2009, the DART System received CE Mark approval for marketing in Europe. To date, the DART System has not received FDA 510K clearance for marketing in the United States.

Other Considerations

Ambrossi and colleagues (2009) examined the incidence of complications after primary discectomy. In 156 consecutive individuals undergoing primary single-level lumbar discectomy, the incidence of symptomatic same-level recurrent disc herniation responding to either conservative therapy or requiring revision discectomy was assessed. Twelve months after surgery, 141 individuals were available for follow-up; of this group, 124 (88%) were symptom free or had minimal symptoms not affecting their daily activity. A total of 17 individuals (12%) developed symptomatic same-level recurrent disc herniation confirmed by imaging at 8 months (median) after primary discectomy. Of this group, 11 (7%) individuals required revision surgery and 6 (3.9%) individuals responded to conservative therapy alone. The authors advocated the development of surgical techniques to prevent recurrent lumbar disc herniation.

Sherman and colleagues (2010) performed a claims-based analysis of individuals having discectomies. Using International Classification of Diseases (ICD) and Current Procedural Terminology (CPT) codes, they identified 497 individuals having discectomies within a 6-month period. A total of 137 (28%) individuals had subsequent insurance claims within 18 months after surgery for additional related treatment. Individuals were studied whose claims included codes for a second operation (n=52, 11%) and those not having a second surgery, but requiring medical or nonsurgical management (n=85, 17%). Of the group requiring a second surgery, 80% had a repeat discectomy and 20% had a spinal fusion. Procedure-related complications within 40 days of surgery were evident in

15% of the group. The authors concluded that development of surgical technologies that improve outcomes of discectomy can positively impact the quality of life.

It has been proposed that improved annular closure procedures may reduce disc reherniation and the need for fusion by the use of devices designed specifically for annulus fibrosus closure. In a review publication, Bron and colleagues (2008) observed that lumbar discectomy is an effective therapy for neurological decompression due to herniated disc. However, there are high recurrence rates of reherniation and persisting post-operative low back pain. The authors noted that suturing techniques for annulus closure have been studied; however, these techniques are directed to containment of the nucleus pulposus and do not compensate the loss of annulus material nor reverse the biomechanical changes that have occurred in the damaged annulus fibrosus. The authors' conclusion proposes that development of techniques that deal with the damaged annulus fibrosus, such as tissue engineering and annulus repair are needed in order to prevent re-herniation.

In 2018, Choy and colleagues published a meta-analysis with the aim to compare current devices to help reduce incidences of recurrent lumbar disc herniation. Two randomized, prospective studies and two non-randomized prospective studies met the inclusion criteria. In the 4 studies, there were a total of 811 subjects that underwent discectomy with an annular closure device with or annular repair (ACD/AR), and 645 subjects that underwent discectomy only. Results showed 24 symptomatic reherniations in the ACD/AR group and 51 symptomatic reherniations were reported in the control group (odds ratio [OR], 0.34; 95% confidence interval [CI], 0.20, 0.56; I^2 =0%; $p<0.0001$). While this study showed a significant reduction in symptomatic disc reherniations, there are several limitations. Only four studies met search criteria, which limited the data, and the included studies had small sample sizes with no long-term follow-up. Larger studies with long-term evaluations of clinical utility are needed.

Background/Overview

The vertebral disc is composed of two parts: the nucleus pulposus and the annulus fibrosus. The nucleus pulposus is a gelatinous substance at the center of the disc and distributes hydraulic pressure in all directions within the disc under compressive loads. The nucleus pulposus consists of chondrocytes, collagen fibrils, and proteoglycan aggregates.

The annulus fibrosus encircles the nucleus pulposus and is made up of tough, fibrous layers. Both structures fit together like two concentric cylinders. The nucleus pulposus bears the axial load of the body and acts as pivot point for movement. The annulus fibrosus acts as a barricade to contain the nucleus pulposus and its hydraulic pressure so it maintains its load bearing and pivot functions.

Definitions

Annulus: The outer fibrous ring of an intervertebral disc; also referred to as annulus fibrosus.

Chondrocyte: A cell that forms cartilage which is the tough, elastic, fibrous connective tissue found in various parts of the body, such as the joints, outer ear, and larynx.

Collagen fibrils: A threadlike fiber or filament that is a constituent of a cell or larger structure.

Herniated disc: A rupture of fibrocartilagenous material (annulus fibrosus) that surrounds the intervertebral disc. This rupture involves the release of the disc's center, the nucleus pulposus, into the spinal column.

Nucleus pulposus: The jelly-like substance in the center of a spinal disc.

Proteoglycan: A type glycoprotein of high molecular weight found in the extracellular matrix of connective tissue.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services are Investigational and Not Medically Necessary:
When the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

CPT

No specific code for annulus closure after annulotomy; not separately reportable

ICD-10 Procedure

For the following procedures when specified as closure using an annular repair device:

0RU30JZ-0RU34JZ	Supplement cervical vertebral disc with synthetic substitute [by approach; includes codes 0RU30JZ, 0RU33JZ, 0RU34JZ]
0RU50JZ-0RU54JZ	Supplement cervicothoracic vertebral disc with synthetic substitute [by approach; includes codes 0RU50JZ, 0RU53JZ, 0RU54JZ]
0RU90JZ-0RU94JZ	Supplement thoracic vertebral disc with synthetic substitute [by approach; includes codes 0RU90JZ, 0RU93JZ, 0RU94JZ]
0RUB0JZ-0RUB4JZ	Supplement thoracolumbar vertebral disc with synthetic substitute [by approach; includes codes 0RUB0JZ, 0RUB3JZ, 0RUB4JZ]
0SU20JZ-0SU24JZ	Supplement lumbar vertebral disc with synthetic substitute [by approach; includes codes 0SU20JZ, 0SU23JZ, 0SU24JZ]
0SU40JZ-0SU44JZ	Supplement lumbosacral disc with synthetic substitute [by approach; includes codes 0SU40JZ, 0SU43JZ, 0SU44JZ]

ICD-10 Diagnosis

All diagnoses

References

Peer Reviewed Publications:

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2. Ardeshiri A, Miller LE, Thomé C. Two-year real-world results of lumbar discectomy with bone-anchored annular closure in patients at high risk of reherniation. Eur Spine J. 2019; 28(11):2572-2578.
3. 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). 2013; 38(14):1161-1169.
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6. Kuršumović A and Rath S. Performance of an annular closure device in a 'real-world', heterogeneous, at-risk, lumbar discectomy population. Cureus. 2017; 9(11):e1824.
7. Parker SL, Grahovac G, Vukas D, et al. 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. 2013; 74(5):285-289.
8. Sherman J, Cauthen J, Schoenberg D, et al. Economic impact of improving outcomes of lumbar discectomy. Spine J. 2010; 10(2):108-116.
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10. Thomé C, Klassen PD, Bouma GJ, et al. Annular closure in lumbar microdiscectomy for prevention of reherniation: a randomized clinical trial. Spine J. 2018; 18(12):2278-2287.
11. Trummer M, Eustacchio S, Barth M, et al. Protecting facet joints post-lumbar discectomy: Barricaid annular closure device reduces risk of facet degeneration. Clin Neurol Neurosurg. 2013; 115(8):1440-1445.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Intrinsic Therapeutics. Study of lumbar discectomy with annular closure. NLM Identifier: NCT03986580. Last updated August 7, 2020. Available at: https://www.clinicaltrials.gov/ct2/show/NCT03986580. Accessed on September 24, 2020.
2. U.S. Food and Drug Administration 510(k) Premarket Notification Database. Xclose Tissue Repair System, Model SRS. Summary of Safety and Effectiveness. No. K062307. Rockville, MD: FDA. September 1, 2006. Available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=k062307. Accessed on August 20, 2020.
3. U.S. Food and Drug Administration Premarket Approval (PMA) Database. Barricaid Anular Closure Device (ACD) Summary of Safety and Effectiveness. No. P160050. Rockville, MD: FDA. February 8, 2019. Available at: https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160050B.pdf. Accessed on August 20, 2020.

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Barricaid Anular Closure Device (ACD)
Disc Annular Repair Technology (DART) System
Inclose Surgical Mesh System
Xclose Tissue Repair System

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

Document History

Status	Date	Action
Reviewed	11/05/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated Rationale and References sections.
Reviewed	11/07/2019	MPTAC review. Updated Rationale, References, and Index sections.
Reviewed	11/08/2018	MPTAC review. Updated Rationale and References sections.
Reviewed	02/27/2018	MPTAC review. The document header wording updated from "Current Effective Date" to "Publish Date." Updated References section.
Reviewed	02/02/2017	MPTAC review. Updated References section.
Reviewed	02/04/2016	MPTAC review. Updated Rationale and References sections. Removed ICD-9 codes from Coding section.
Reviewed	02/05/2015	MPTAC review. Format changes throughout document sections.
Reviewed	02/13/2014	MPTAC review. Updated Rationale, References, and Index sections.
	07/23/2013	Updated Rationale and Reference sections with peer-reviewed published literature addressing the Xclose Tissue Repair System and Barricaid devices.
Reviewed	02/14/2013	MPTAC review. Clarified the Description. Updated the Rationale, Definitions, References, and Index.
New	02/16/2012	MPTAC review. Initial document development.