Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 11/1/24**
(See policy history boxes for previous effective dates)

Title: Annular Closure Devices (e.g., Barricaid®, Xclose®, Inclose™)

Description/Background

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.

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.

Regulatory Status

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.

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.

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.

Medical Policy Statement

The use of annular closure devices (e.g., Xclose®, Barricaid®, DART system, Inclose™) following a discectomy is experimental/investigational. It has not been shown to improve clinical health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

64999 C9757

Note: Individual policy criteria determine the coverage status of the CPT/HCPCS code(s) on this policy. Codes listed in this policy may have different coverage positions (such as established or experimental/investigational) in other medical policies.

Rationale

Xclose® Tissue Repair System
The Xclose Tissue Repair System (modified sutures with anchors) was proposed for re-approximation of the annulus fibrosus after a lumbar discectomy procedure.

Bailey et al (2013) completed a two-year follow up evaluation to outcomes associated with repairing annulus fibrosus after lumbar discectomy.[1] 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 the difference between the two groups in reoperation for disc reherniation was not seen at two years. 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 two-year follow-up for inclusion in the analysis. The authors concluded that the

addition of annulus fibrosus repair did not induce a significant reduction in reoperation for recurrent herniation. Additional RCTs 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 is proposed as an alternative procedure for annular repair following discectomy to reapproximate 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® Annular Closure Device (ACD)

Trummer et al (2013) investigated whether implantation with the Barricaid annular closure device (ACD) during discectomy reduced the rate of facet degeneration.[2] Inclusion criteria were primary lumbar disc herniation failing conservative treatment, Visual Analog Scale (VAS) Leg≥40/100, Oswestry Disability Index (ODI)≥40/100 and defects that were ≤60 mm2 (Barricaid arm only), and patient age 18-75. CT interpretations were collected preoperatively and 12 months post-discectomy. Patients implanted with Barricaid had significantly reduced rates and grades of facet degeneration than patients without Barricaid. Reinforcing the annulus fibrosus with Barricaid during lumbar discectomy may slow the progression of facet joint degeneration.

Parker et al (2016) evaluated whether an annular closure device could be implanted safely to reduce same-level recurrent disk herniation, or attenuate disk height loss and improve the outcome after lumbar discectomy.[3] Forty-six consecutive patients undergoing lumbar discectomy for single-level herniated disk at 2 institutions were followed prospectively with clinical and radiographic evaluations at 6 weeks and 3, 6, 12, and 24 months (control cohort). A second consecutive cohort of 30 patients undergoing 31 lumbar discectomies with implantation of an annular closure device was followed similarly. Incidence of recurrent disk herniation, disk height loss, the leg and back pain visual analog scale (VAS), and the Oswestry Disability Index were assessed at each follow-up. Cohorts were well matched at baseline. By 2 years of follow-up, symptomatic recurrent same-level disk herniation occurred in 3 (6.5%) patients in the control cohort versus 0 (0%) patients in the annular repair cohort (P=.27). A trend of greater preservation of disk height was observed in the annular repair versus the control cohort 3 months (7.9 vs. 7.27 mm, P=.08), 6 months (7.81 vs. 7.18 mm, P=.09), and 12 months (7.63 vs. 6.9 mm, P=.06) postoperatively. The annular closure cohort reported less leg pain (VAS-LP: 5 vs. 16, P<.01), back pain (VAS-BP: 13 vs. 22, P<.05), and disability (Oswestry Disability Index: 16 vs. 22, P<.05) 1 year postoperatively. Implantation of a novel annular repair device was associated with greater maintenance of disk height and improved 1-year leg pain, back pain, and low-back disability. Recurrent disk herniation did not occur in any patient after annular repair. Closure of annular defect after lumbar discectomy may help preserve the physiological disk function and prevent long-term disk height loss and associated back and leg pain.

An assessment of annulus fibrosus repair after lumbar discectomy by the Ludwig Boltzmann Institute for Health Technology Assessment (Semlitsch & Geiger-Gritsch, 2019) found that the closure of annular defects after discectomy using the Barricaid device could be a meaningful intervention for a selected group of patients with a large annular defect to prevent reherniations and reoperations.[4] However, a significant number of patients experienced problems with device integrity over a period of two years. In addition, these results are based on a few studies with a high risk of bias and published long-term results beyond a period of two years are missing. Similar results in terms of clinical effectiveness and safety were obtained for the Xclose system. However, only results from a single randomized controlled trial with a high risk of bias are available.

In 2018, Choy et al performed a meta-analysis to assist surgeons on determining a potential approach to reducing incidences of recurrent lumbar disc herniation and assess the current devices regarding their outcomes and complications.[5] Four studies met inclusion criteria. Three studies reported the use of Barricaid (ACD) while one study reported the use of Anulex (AR). A total of 24 symptomatic reherniation were reported among 811 discectomies with ACD/AR as compared to 51 out of 645 in the control group (OR: 0.34; 95% CI: 0.20,0.56; I2 = 0%; P<.0001). Durotomies were lower among the ACD/AR patients with only 3 reported cases compared to 7 in the control group (OR: 0.54; 95% CI: 0.13, 2.23; I2 = 11%; P=.39). Similar outcomes for post-operative Oswestry Disability Index and visual analogue scale were obtained when both groups were compared. Early results show the use of Barricaid and Anulex devices may be beneficial for short term outcomes demonstrating reduction in symptomatic disc reherniation with low post-operative complication rates. Long-term studies are required to further investigate the efficacy of such devices.

Thome et al (2018) presented a multicenter, randomized superiority study on whether a bone-anchored annular closure device in addition to lumbar microdiscectomy would result in lower reherniation and reoperation rates plus increased overall success compared with lumbar microdiscectomy alone.[6] Patients with symptoms of lumbar disc herniation for at least 6 weeks with a large annular defect (6-10 mm width) after lumbar microdiscectomy were included in the study. Patients received lumbar microdiscectomy with additional bone-anchored annular closure device (n=276 participants) or lumbar microdiscectomy only (control; n=278 participants). This research was supported by Intrinsic Therapeutics (Barricaid). Two authors received study-specific support more than $10,000 per year, 8 authors received study-specific support less than $10,000 per year, and 11 authors received no study-specific support. Among 554 randomized participants, 550 (annular closure device: n=272; control: n=278) were included in the modified intent-to-treat efficacy analysis and 550 (annular closure device: n=267; control: n=283) were included in the as-treated safety analysis. Both co-primary end points of the study were met, with recurrent herniation (50% vs. 70%, P<.001) and composite end point success (27% vs. 18%, P=.02) favoring annular closure device. The frequency of symptomatic reherniation was lower with annular closure device (12% vs. 25%, P<.001). There were 29 reoperations in 24 patients in the annular closure device group and 61 reoperations in 45 control patients. The frequency of reoperations to address recurrent herniation was 5% with annular closure device and 13% in controls (P=.001). End plate changes were more prevalent in the annular closure device group (84% vs. 30%, P<.001). Scores for back pain, leg pain, Oswestry Disability Index, and health-related quality of life at regular visits were comparable between groups over 2 year follow-up. The authors concluded that patients at high risk of herniation recurrence after lumbar microdiscectomy, annular closure with a bone-anchored

implant could lower the risk of symptomatic recurrence and reoperation. However the authors caution that additional study to determine long-term outcomes is warranted.

In a randomized, multi-center trial, Nanda et al (2019) examined if implanting an annular closure device (ACD) following lumbar discectomy in patients with large defects in the annulus fibrosus lowers the risk of re-operation after 4 years.[7] Patients with large annular defects following single level lumbar discectomy were intra-operatively randomized to additionally receive an ACD or no treatment (controls). Clinical and imaging follow-up were performed at routine intervals over 4 years of follow-up. Main outcomes included re-operations at the treated lumbar level, leg pain scores on a visual analog scale (VAS), Oswestry Disability Index (ODI), and Physical Component Summary (PCS) and Mental Component Summary (MCS) scores from the SF-36 questionnaire. Among 550 patients (ACD 272, control 278), the risk of re-operation over 4 years was 14.4 % with ACD and 21.1 % with controls (p=.03). The reduction in re-operation risk with ACD was not significantly influenced by patient age (p=.51), sex (p=.34), body mass index (BMI; p=.21), smoking status (p=.85), level of herniation (p =.26), leg pain severity at baseline (p=.90), or ODI at baseline (p=.54). All patient-reported outcomes improved in each group from baseline to 4 years (all p<.001). The percentage of patients who achieved the minimal clinically important difference without a re-operation was proportionally higher in the ACD group compared to controls for leg pain (p=.07), ODI (p=.10), PCS (p=.02), and MCS (p=.06). The authors concluded that the addition of a bone-anchored ACD following lumbar discectomy in patients with large post-surgical annular defects reduced the risk of re-operation and provided better long-term pain and disability relief over 4 years compared to lumbar discectomy only. The authors stated that this study had several drawbacks. First, the results presented were applicable only to patients with large post-discectomy annular defects, who accounted for approximately 30 % of all lumbar discectomy cases. Implantation of an ACD in patients with small annular defects cannot be justified clinically given the inherently low risk of symptom recurrence in these individuals. Additional patient characteristics that were crucial to achieving positive results included adequate disc height and non-osteoporotic bone mineral density (BMD) of the lumbar spine. Second, the decision to re-operate involved shared decision-making between the patient and surgeon and, thus, there was potential for bias in the reported re-operation rates. Finally, 5 year follow- up in this study is ongoing and these long-term outcomes are anxiously awaited to provide final comparative efficacy, safety, and cost-utility results of bone-anchored ACD implantation.

In 2021, Thome et al performed a secondary analysis of a multicenter RCT reporting on a 5-year follow-up for patients implanted with the Barricaid annular device.[9] Among 554 randomized participants (mean [SD] age: 43 [11] years; 327 [59%] were men), 550 were included in the modified intent-to-treat efficacy population (device group: n = 272; 270 [99%] were White); control group: n = 278; 273 [98%] were White) and 550 were included in the as-treated safety population (device group: n = 267; control group: n = 283). The risk of symptomatic reherniation (18.8% [SE, 2.5%] vs 31.6%[SE, 2.9%]; P<.001) and reoperation (16.0% [SE, 2.3%] vs 22.6%[SE, 2.6%]; P=.03) was lower in the device group. There were 53 reoperations in 40 patients in the device group and 82 reoperations in 58 patients in the control group. Scores for leg pain severity, Oswestry Disability Index, and health-related quality of life significantly improved over 5 years of follow-up with no clinically relevant differences between groups. The frequency of serious adverse events was comparable between the treatment groups. Serious adverse events associated with the device or procedure were less frequent in the device group (12.0% vs 20.5%; difference, −8.5%; 95%CI, −14.6%to −2.3%; P=.008).

The authors stated that this study had several drawbacks. First, the results were generalizable only to patients with large defects in the annulus fibrosus following lumbar discectomy. Second, most patients and all investigators were aware of treatment assignment; thus, it was possible that re-operation rates may have been influenced by performance bias. Third, patients in the trial were treated with limited lumbar discectomy with little to no removal of disc material within the intervertebral space. It was possible that lower re-herniation rates could be achieved with aggressive disc resection, although intervertebral instability and spondylosis progression were potential risks with this surgical technique. Fourth, although end-plate changes in the device group were associated with a benign clinical course through 5 years of follow-up, their natural history over longer term follow-up is currently unclear. Finally, although the 5-year follow-up visit rate of 73 % was typical of long-term clinical trials of spinal devices, the potential for bias owing to missing data must be acknowledged.

Disc Annular Repair Technology (DART) System

The DART System implant is said to provide 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.

SUMMARY OF EVIDENCE

For individuals who have had a lumbar discectomy with an Xclose® or Barricaid® annular closure device the evidence includes a randomized clinical trial, some cohort studies and a meta-analysis. The studies purport that reinforcing the annulus fibrosus with an annular closure device during lumbar discectomy may slow the progression of facet joint degeneration and preserve the physiological disc function. These results are based on a few studies with a high-risk of bias. In addition, some studies did not show a statistically significant improvement in clinical outcomes or decrease in overall complication rates. Additional studies to determine long-term outcomes is required. 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.

For individuals who have had a lumbar discectomy with Inclose™ Surgical Mesh System or the DART system there are no studies currently published in the peer-reviewed medical literature to support the safety and efficacy of these technologies, or that it would improve net health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

International Society for the Advancement of Spine Surgery (ISASS)

In 2019, ISASS posted a policy guideline relating to lumbar disc herniation with radiculopathy, including the implantation of a bone-anchored annular closure device (Barricaid) in patients with large annular defects.[9]

ONGOING AND UNPUBLIDED CLINICAL TRIALS

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03366779	A post marketing surveillance study (6MM)	20	Dec 2024
NCT03986580	Study of lumbar discectomy with annular closure	55	Dec 2024
NCT01283438	A prospective, randomized, multicenter study to demonstrate the superiority of the Barricaid to discectomy for primary lumbar disc herniation	554	June 2025
NCT05467072	PMCFU of an annular closure system	250	Oct 2024
Unpublished			
NCT00760799*	Randomized study of annular repair with the Xclose tissue repair system	750	Jan 2012
NCT01534065*	Barricaid EU post market study for primary lumbar disc herniation	45	Mar 2013

NCT: National clinical trial;
*Sponsored or cosponsored by the manufacturer

Government Regulations

National:

No NCD found on this topic.

Local:

No LCD found on this topic.

MLN Matters Number: MM11607, effective January 1, 2020, section 2: New separately payable procedure codes. Code C9757 is listed as a separately payable code.[10]

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Spinal Surgery—Minimally Invasive Lumbar Interbody Fusion (LIF)
- Spinal Surgery—Percutaneous Disc Decompression Using Laser Energy or Radiofrequency Ablation (Nucleoplasty)
- Spinal Surgery—Percutaneous Intradiscal Electrothermal (IDET) Annuloplasty, Radiofrequency Annuloplasty, and Biacuplasty
- Spinal Surgery—Automated Percutaneous and Endoscopic Discectomy

References

1. Bailey A, Araghi A, Blumenthal S, et al. Prospective, multicenter, randomized, controlled study of anular repair in lumbar discectomy: two-year follow-up. Spine (Phila Pa 1976). 2013; 38(14):1161-1169.
2. Trummer M, Eustacchio S, Barth M, et al. Protecting facet joints post-lumbar discectomy: Barricaid annular closure device reduces risk of facet degeneration. Clineuro. 2013; 115(8):1440-1445.
3. Parker et al 2016. Effect of an Annular Closure Device (Barricaid) on Same-Level Recurrent Disk Herniation and Disk Height Loss After Primary Lumbar Discectomy: Two-year Results of a Multicenter Prospective Cohort Study. Clinical spine surgery, 29(10), 454–460. https://doi.org/10.1097/BSD.0b013e3182956ec5
4. Semlitsch T, Geiger-Gritsch S. Annulus fibrosus repair after lumbar discectomy. Executive Summary. Decision Support Document 65/Update 2019). Ludwig Boltzmann Institute, Health Technology Assessment; 2019.
5. Choy WJ, Phan K, Diwan AD, et al. Annular closure device for disc herniation: meta-analysis of clinical outcomes and complications. BMC Musculoskelet Disord. 2018; 19(1): 290-292.
6. Thome C, Klassen PD, Bouma JG, et al. Annular closure in lumbar microdiscectomy for prevention of reherniation: a randomized clinical trial. J Spinee. 2018; 18(12):2278-2287.
7. Nanda D, Arts M, Miller L, et al. Annular closure device lowers reoperation risk 4 years after lumbar discectomy. MDER. 2019; 12: 327-335.
8. Thome C, Kursumovic A, Klassen PD, et al; Annular Closure RCT Study Group. Effectiveness of an annular closure device to prevent recurrent lumbar disc herniation: A secondary analysis with 5 years of follow-up. JAMA Netw Open. 2021;4(12):e2136809.
9. Lorio M, Kim C, Araghi A, et al. ISASS policy guideline—surgical treatment of lumbar disc herniation with radiculopathy. 2019. Available at: https://www.isass.org/isass-policy-guideline-surgical-treatment-of-lumbar-disc-herniation-with-radiculopathy/. Last accessed June 2024.
10. Centers for Medicare and Medicaid. MLN Matters®. January 2020 Update of the Ambulatory Surgical Center (ASC) Payment System. MM11607. 2020.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through June 20, 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
11/1/20	8/18/20		Joint policy established
11/1/21	8/17/21		Routine Maintenance
11/1/22	8/16/22		Routine policy maintenance, added reference #9. No change in policy status.
11/1/23	8/15/23		Routine policy maintenance. No change in policy status. Vendor: Turningpoint (ky)
11/1/24	8/20/24		Routine policy maintenance. No change in policy status. Vendor: Turningpoint (ky)

Next Review Date: 3rd Qtr. 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: ANNULAR CLOSURE DEVICES (E.G., BARRICAID®, XCLOSE®, INCLOSE™)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	See government section
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.