Medical Policy Manual Surgery, Policy No. 243

Annular Closure Devices

Effective: April 1, 2026

Next Review: November 2026
Last Review: November 2025

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

An annular closure device is a treatment used following spinal decompression/discectomy and has been proposed as a mechanism to reduce the risk of disc reherniation.

MEDICAL POLICY CRITERIA

The use of an annular closure device for any indication is considered **investigational.**

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

REGULATORY STATUS

The Barricaid® ACD (Intrinsic Therapeutics, Inc., Woburn, MA) received FDA premarket approval in February 2019. The device is indicated for reducing the incidence of reherniation and reoperation in skeletally mature patients with radiculopathy.

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

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

EVIDENCE SUMMARY

Systematic Reviews

Dalal (2025) published a systematic review and meta-analysis including five studies on the effects of annular closure devices (ACD) on reherniation rates, complication rates, and pain outcomes.[1] Included in the analysis are two RCTs, two retrospective studies, and a prospective cohort study. Symptomatic reherniation rates in the ACD populations ranged from 3% to 18.8%. Two studies found that control groups herniate significantly more than their ACD counterparts (ACD 18.8% vs non-ACD 31.6% and ACD 3.33% vs non-ACD 20.0%). No significant differences were found in reoperation rates. Of the four studies that reported patient-reported outcome measures, all observed relative improvement in each cohort, although pooled analysis did not find significant differences between ACD and non-ACD groups for Oswestry Disability Index and visual analogue scale-leg pain at two-year follow-up. This review is limited by the heterogeneity of the included studies, lack of blinding in the randomized trials, and unclear follow-up in the included retrospective cohort study. Additionally, there may be bias introduced by the funding received from the manufacturer for several of the authors of the included studies.

Wang (2024) published a review and meta-analysis of annulus fibrosus repair for lumbar disc herniation including a sub-group analysis of those receiving an ACD.[2] Combined data analysis indicated that adding an annular repair technique lowered postoperative recurrence, reduced reoperation rates, and minimized loss of intervertebral height compared to lumbar discectomy alone. Subgroup analysis of different annular repair methods showed that the Barricaid Annular Closure Device (ACD) effectively prevented re-protrusion and decreased reoperation rates, while no significant differences were found among the other subgroups. This review is limited due to the study design of the included study and potential bias introduced by the funding received from the manufacturer for several of the authors of the included studies.

Miller (2020) published a systematic review and meta-analysis of the Barricaid annular device in patients at high risk for lumbar disc reherniation.[3] Four trials (two RCTs) were included in the meta-analysis. The trial by Thomé (2018) summarized below was the only trial to find a significant decrease in symptomatic reherniation or reoperation at two years.[4] The other three trials all indicated nonsignificant reduction for both outcomes. Overall, results of the meta-analysis favored the use of an annular device for post-discectomy patients with large annular defects.

Randomized Controlled Trials

Thomé (2018) conducted an open-label RCT comparing lumbar discectomy alone or lumbar discectomy with annular closure.[4] A total of 554 patients who had failed nonsurgical treatment

and had a disc height of at least 5 mm were randomized. Results at two years are summarized in Table 6. Longer follow-up data at 3 years found continued lower risk of reherniation (14.8% vs. 29.5%; p<.001) and reoperation (11% vs. 19.3%; p=.007) in patients receiving an annular closure device.[5] At 5-year follow-up, the risk of symptomatic reherniation (18.8% vs. 31.6%; p<.001) and reoperation (16.0% vs. 22.6%; p=.03) remained lower in patients receiving an annular closure device.[6] None of the investigators were blind to treatment assignment, and only patients at specific sites were blind.

Cho (2019) published a smaller RCT conducted solely in Korea.[7] Patients were followed for 24 months and the primary endpoint of the trial was disc height. Patients treated with an annular closure device maintained disc height at 24 months to a greater extent than those with discectomy alone (86.3% vs. 79.2%; p=.04). Back pain and leg pain were similarly improved in both treatment groups. Recurrent herniation was more common with discectomy alone. The small sample size, large loss to follow-up (≤70% at 2-year follow-up), and unclear blinding limit the validity of this trial.

Section Summary: Lumbar Discectomy with Annular Closure Device
For individuals who have lumbar herniated disc(s) and undergo discectomy, use of a bone-anchored annular closure device has been evaluated as a means to reduce reherniation and reoperation in a systematic review and RCTs. The systematic reviews have identified two RCTs and several nonrandomized trials and found reduced reherniation and reoperation with the addition of the annular closure device to lumbar discectomy. The primary RCT for the bone-anchored annular closure device found reduced reherniation and reoperation at up to 5 years of follow-up. The included reviews are limited by the heterogeneity of the included studies, lack of blinding in the randomized trials, and unclear follow-up in the included retrospective cohort study. Additionally, there may be bias introduced by the funding received from the manufacturer for several of the authors of the included studies.

PRACTICE GUIDELINE SUMMARY

In 2019, the International Society for the Advancement of Spine Surgery included specific recommendations for bone-anchored annular closure devices as follows[8]:

- "Patient is indicated for a primary discectomy due to a posterior or posterolateral herniation,
- Discectomy will be performed at a single level that includes L4-L5 or L5-S1,
- The annular defect is large (between 4 and 6 mm tall and between 6 and 10 mm wide) after completion of the discectomy procedure."

SUMMARY

There is not enough research to show that the use of annular closure devices improves net health outcomes for any indication. Therefore, the use of annular closure devices for any indication is considered investigational.

REFERENCES

1. Dalal S, Araghi K, Mai E, et al. Annular Closure Device Reduces Symptomatic Reherniation Rates: Results of a Meta-analysis. *Hss j.* 2025;21(1):55-64. PMID: 39846061
2. Wang Y, He X, Chen S, et al. Annulus Fibrosus Repair for Lumbar Disc Herniation: A Meta-Analysis of Clinical Outcomes From Controlled Studies. *Global Spine J.* 2024;14(1):306-21. PMID: 37068762
3. Miller LE, Allen RT, Duhon B, et al. Expert review with meta-analysis of randomized and nonrandomized controlled studies of Barricaid annular closure in patients at high risk for lumbar disc reherniation. *Expert Rev Med Devices.* 2020;17(5):461-69. PMID: 32237917
4. 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):2278-87. PMID: 29730458
5. Kienzler JC, Klassen PD, Miller LE, et al. Three-year results from a randomized trial of lumbar discectomy with annulus fibrosus occlusion in patients at high risk for reherniation. *Acta Neurochir (Wien).* 2019;161(7):1389-96. PMID: 31089894
6. Thomé C, Kuršumovic A, Klassen PD, et al. 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. PMID: 34882183
7. Cho PG, Shin DA, Park SH, et al. Efficacy of a Novel Annular Closure Device after Lumbar Discectomy in Korean Patients : A 24-Month Follow-Up of a Randomized Controlled Trial. *J Korean Neurosurg Soc.* 2019;62(6):691-99. PMID: 31679318
8. Lorio M, Kim C, Araghi A, et al. International Society for the Advancement of Spine Surgery Policy 2019-Surgical Treatment of Lumbar Disc Herniation with Radiculopathy. *Int J Spine Surg.* 2020;14(1):1-17. PMID: 32128297

CODES

Codes	Number	Description
CPT	63032	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; with repair of annular defect by implantation of bone anchored annular closure device, including all imaging guidance, 1 interspace, lumbar (List separately in addition to code for primary procedure)
HCPCS	C9757	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar

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