Barricaid® Annular Closure Device

Spine, Pain, and Joint (SPJ) Utilization Management Policy

Approval Date: 03/05/2026

Table of Contents

Policy Statement

The Barricaid® Annular Closure Device (ACD) is considered unproven and not medically necessary. There is insufficient high-quality evidence to determine the efficacy of annulus fibrosus repair devices, such as the Barricaid® ACD, as an adjunctive treatment for discectomy.

For Medicare beneficiaries, refer first to any relevant local coverage determinations (LCDs) and then to the Medicare Benefit Policy Manual, section 16.20, for services considered not reasonable and necessary.

Scope

All in and out of network programs where utilization review determinations are rendered. This policy also serves as a resource for peer-to-peer interactions in describing the position of Optum on the reporting of the Barricaid® Annular Closure Device.

Background Information

In February 2019, the Barricaid® ACD (Intrinsic Therapeutics) received premarket approval by the FDA (P160050). The Barricaid® ACD 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 annular 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 [FDA], 2019).

The Barricaid® Annular Closure Device is implanted at the time of a lumbar discectomy, after the discectomy is complete. The Barricaid® is a permanent implant that has two major subcomponents: a flexible woven polymer fabric component is intended to close the annular defect, and a bone anchor to affix the flexible polymer component in place. The Barricaid® serves as an adjunct to the discectomy procedure and is intended to function as a barrier to block the annular defect that is identified as part of the discectomy. (FDA, 2019).

Clinical Evidence

Dalal et al. (2025) conducted a systematic review and meta-analysis to evaluate long-term postoperative outcomes of the Barricaid® Annular Closure Device (ACD). The meta-analysis included two randomized controlled trials, two retrospective studies, and one prospective cohort study, all published after 2015 with at least two years of follow-up (mean 2.6 years) and inclusion of reherniation and complication rates. Reported symptomatic reherniation rates in ACD patients ranged from 3% to 18.8%, with two studies demonstrating significantly lower reherniation compared with non-ACD controls, though no significant differences emerged in reoperation rates. Among four studies reporting patient-reported outcome measures, all groups improved over time, yet pooled analyses showed no significant differences between ACD and non-ACD cohorts in Oswestry Disability Index or leg pain scores at two years. Limitations include the small number of eligible studies, heterogeneity in study design and reporting, and incomplete PROMs data, which restrict generalizability. While evidence suggests that the Barricaid® device may reduce symptomatic reherniation following discectomy, it does not appear to improve functional outcomes or reoperation rates, and potential device-related complications should be considered.

Wang et al. (2024) aimed to summarize the clinical efficacy and safety of annular repair techniques for patients with lumbar disc herniation (LDH). This meta-analysis synthesized 15 studies—seven randomized controlled trials and eight observational studies—comprising a total of 2,161 participants who underwent annular repair during treatment for LDH. Safety outcomes were similar between repair and control (discectomy alone) groups, with no significant increase in adverse events. Authors concluded that

discectomy combined with Barricaid® Annular Closure Device (ACD) reduced postoperative recurrence, reoperation rates, and intervertebral height loss compared with discectomy alone, while annulus fibrosus suture (AFS) did not significantly improve functional outcomes or reduce pain in patients with LDH. However, the evidence is limited by the inclusion of both randomized and observational studies, potential heterogeneity across repair techniques, and the relatively small number of studies per subgroup, which may reduce the precision and generalizability of the findings.

The ECRI Evidence Analysis reported that the Barricaid® Annular Closure Device, used as an adjunct to lumbar microdiscectomy in patients with large annular defects, is associated with reduced rates of recurrent disc herniation and reoperation compared with discectomy alone, based on a systematic review and supporting randomized and nonrandomized studies. Evidence suggests similar long-term pain, disability, and quality-of-life outcomes between groups, with some short-term studies showing modest pain improvements in Barricaid® recipients. Serious device- or procedure-related adverse events appear lower with Barricaid®, though risks such as dural injury, nerve root injury, and device migration exist. Major limitations include reliance on several nonrandomized studies at risk of bias, limited geographic diversity (studies primarily in Europe and South Korea), and uncertain generalizability to U.S. practice. Overall, while evidence is somewhat favorable, higher-quality U.S.-based RCTs and direct comparisons with other annular closure methods are needed to strengthen conclusions. (ECRI, 2023).

A Hayes Technology Assessment evaluated annular closure device (ACD) implantation as an adjunct to lumbar discectomy for treatment of sizable annular defects (usually ≥ 6 mm) with the goal of reducing risk of lumbar disc herniation (LDH) recurrence in adult patients whose LDH is refractory to conservative treatment. A generally low-quality body of evidence indicates that adding an ACD to lumbar discectomy may offer modest benefits, including slight improvements in pain, quality of life, and disc height, along with lower rates of reherniation and reoperation over 2 to 5 years. However, ACD implantation consistently lengthens surgical time and is supported primarily by studies with methodological limitations, such as limited randomization, small sample size, retrospective analysis, use of a historical control group, and short follow-up durations. Most reported complications were mild to moderate, though some serious adverse events—such as symptomatic reherniation, device failure, and wound issues—did occur. (Hayes, 2025).

Li et al. (2023) performed a systematic review and meta-analysis of five randomized controlled trials (2,380 patients) to compare lumbar discectomy with and without annular closure device (ACD) implantation. ACD significantly reduced rates of reherniation (7.4% vs 17.6%), reoperation (5.4% vs 13.6%), and serious adverse events (10.8% vs 17.1%) compared to controls. No significant differences were observed in pain scores, disability, or quality of life. Subgroup analysis of limited lumbar discectomy showed similar trends, with lower reherniation and reoperation rates in the ACD group. Overall, ACD implantation improves safety and reduces recurrence risk without altering functional outcomes, though cost-effectiveness and procedure-specific impacts warrant further study.

Thomé et al. (2021) performed a secondary analysis of a multicenter randomized clinical trial to evaluate 5-year outcomes of lumbar microdiscectomy with or without a bone-anchored annular closure device in patients with large annular defects (6–10 mm). Among 554 participants, the device group had significantly lower rates of symptomatic reherniation (18.8% vs 31.6%; $P < .001$) and reoperation (16.0% vs 22.6%; $P = .03$) compared to controls. Both groups showed substantial improvements in leg pain, disability, and quality of life, with no clinically meaningful differences between them. Serious adverse events were similar overall but less frequent in the device group when related to the device or procedure (12.0% vs 20.5%; $P = .008$). These findings suggest that annular closure with a bone-anchored implant reduces long-term recurrence and reoperation risk in high-risk patients without compromising clinical outcomes.

A multicenter randomized superiority trial conducted by Thomé et al. (2018) compared lumbar microdiscectomy with and without a bone-anchored annular closure device in patients with large annular defects (6–10 mm). Among 554 participants, both co-primary endpoints were met at 2-year follow-up: recurrent herniation was significantly lower with the device (50% vs 70%, $P < .001$), and composite success was higher (27% vs 18%, $P = .02$). Symptomatic reherniation occurred in 12% of device patients versus 25% of controls, and reoperations for recurrence were reduced (5% vs 13%, $P = .001$). Endplate changes were more frequent with the device (84% vs 30%, $P < .001$), but pain, disability, and quality-of-

life scores were similar between groups. Overall, annular closure reduced recurrence and reoperation risk in high-risk patients, though long-term outcomes beyond 2 years require further study.

Coding Information

Note: The Current Procedural Terminology (CPT) codes (2026) listed in this policy may not be all inclusive and are for reference purposes only. The listing of a service code in this policy does not imply that the service described by the code is a covered or non-covered health service. Coverage is determined by the member's benefit document.

Code	Description
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar.
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)

References

American Medical Association. (2025). CPT 2026 Professional Edition. American Medical Association Press.

Centers for Medicare and Medicaid Services. (2025, June 18). Medicare benefit policy manual chapter 16: General exclusions from coverage. Rev. 13272. Retrieved January 6, 2026, from: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c16.pdf#page=3&zoom=100,117,816

Dalal, S., Araghi, K., Mai, E., et al. (2025). Annular Closure Device Reduces Symptomatic Reherniation Rates: Results of a Meta-analysis. HSS Journal: The Musculoskeletal Journal of Hospital for Special Surgery, 21(1), 55–64. https://doi.org/10.1177/15563316231215796

ECRI Institute (2023, June 9). Evidence Analysis: Barricaid Annular Closure Device (Intrinsic Therapeutics, Inc.) for preventing recurrent vertebral disc herniation after lumbar discectomy. Retrieved December 22, 2025 from . https://members.ecri.org/evidenceanalysis/barricaid-annular-closure-device-intrinsic-therapeutics-inc-for-preventing-

Hayes, Inc. (2025, July 18). Health Technology Assessment: Annular closure for prevention of lumbar disc reherniation. Retrieved December 22, 2025 from https://evidence.hayesinc.com/report/dir.annular5060

Li, W. S., Li, G. Y., Yan, Q., et al. (2023). The Effectiveness and Safety of Annulus Closure Device Implantation in Lumbar Discectomy for Patients with Lumbar Disc Herniation: A Systematic Review and Meta-analysis. European Spine Journal: Official Publication of the European Spine Society, the European Spinal Deformity Society, and the European Section of the Cervical Spine Research Society, 32(7), 2377–2386. https://doi.org/10.1007/s00586-023-07629-0

Thomé, C., Klassen, P. D., Bouma, G. J., et al. (2018). Annular closure in lumbar microdiscectomy for prevention of reherniation: a randomized clinical trial. The spine journal : official journal of the North American Spine Society, 18(12), 2278–2287. https://doi.org/10.1016/j.spinee.2018.05.003

Thomé, C., Kuršumovic, A., Klassen, P. D., et al. (2021). Effectiveness of an Annular Closure Device to Prevent Recurrent Lumbar Disc Herniation: A Secondary Analysis with 5 Years of Follow-up. JAMA Network Open, 4(12), e2136809. https://doi.org/10.1001/jamanetworkopen.2021.36809

U.S. Food and Drug Administration (2019, February 19). Barricaid® Annular Closure Device. Premarket Approval (P160050). Summary of Safety and Effectiveness Data. Retrieved January 6, 2026, from https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P160050

Wang, Y., He, X., Chen, S., et al. (2024). Annulus Fibrosus Repair for Lumbar Disc Herniation: A Meta-Analysis of Clinical Outcomes From Controlled Studies. Global Spine Journal, 14(1), 306–321. https://doi.org/10.1177/21925682231169963

Review and Approval History

Date	Description
02/10/2026	New policy developed. Approved by Optum Clinical Guideline Advisory Committee.
03/05/2026	Approved by UM Quality Oversight Committee (QOC).