Policy Number	SUR705.045
Policy Effective Date	12/01/2025
Policy End Date	10/31/2026

Annulus Closure After Discectomy

Table of Contents
Coverage
Policy Guidelines
Description
Rationale
Coding
References
Policy History

Related Policies (if applicable)
None

Disclaimer

Carefully check state regulations and/or the member contract.
Each benefit plan, summary plan description or contract defines which services are covered, which services are excluded, and which services are subject to dollar caps or other limitations, conditions or exclusions. Members and their providers have the responsibility for consulting the member's benefit plan, summary plan description or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. **If there is a discrepancy between a Medical Policy and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern.**

Coverage

The use of an annular closure device (e.g., Barricaid®) following discectomy **is experimental, investigational, and/or unproven.**

Policy Guidelines

None.

Description

Disc Herniation
Extrusion of an intervertebral disc beyond the intervertebral space can compress the spinal nerves and result in symptoms of pain, numbness, and weakness.

The natural history of untreated disc herniations is not well-characterized, but most herniations will decrease in size over time due to shrinking and/or regression of the disc. (1) Clinical

symptoms will also tend to improve over time in conjunction with shrinkage or regression of the herniation.

Treatment

Because most disc herniations improve over time, initial care is conservative, consisting of analgesics and a prescribed activity program tailored to patient considerations. Other potential nonsurgical interventions include opioid analgesics and chiropractic manipulation. Epidural steroid injections can also be used as a second-line intervention and are associated with short-term relief of symptoms. (2)

However, some disc herniations will not improve over time with conservative care. A small proportion of patients will have rapidly progressive signs and symptoms, thus putting them at risk for irreversible neurologic deficits. These patients are considered to be surgical emergencies, and expedient surgery is intended to prevent further neurologic deterioration and allow for nerve recovery.

Other patients will not progress but will have the persistence of symptoms that require further intervention. It is estimated that up to 30% of patients with sciatica will continue to have pain for more than 1 year. (3) For these patients, there is a high degree of morbidity and functional disability associated with chronic back pain, and there is a tendency for recurrent pain despite treatment. Therefore, treatments that have more uniform efficacy for patients with a herniated disc and chronic back pain are needed. In particular, decreased chronic pain and decreased disability are the goals of treatment of chronic low back pain due to a herniated disc.

Surgical Treatment

Discectomy is a surgical procedure in which one or more intervertebral discs are removed. The primary indication for discectomy is herniation (extrusion) of an intervertebral disc. Discectomy is intended to treat symptoms by relieving pressure on the affected nerve(s).

Lumbar discectomy can be performed by a variety of surgical approaches. Open discectomy is the traditional approach. In open discectomy, a 2- to 3-cm incision is made over the area to be repaired. The spinal muscles are dissected, and a portion of the lamina may be removed to allow access to the vertebral space. The extruded disc is removed either entirely or partially using direct visualization. Osteophytes that are protruding into the vertebral space can also be removed if deemed necessary.

In patients with large annular defects following lumbar discectomy, annular closure devices have been proposed to reduce the risk of recurrence and reoperation. (4) Although many devices and techniques have been investigated, a bone-anchored implant is the only device currently approved by the Food and Drug Administration (FDA).

Regulatory Status

Barricaid®, a bone-anchored annular closure device, was approved by the FDA in 2019 for use in patients with large annular defects (4-6 mm tall and 6-10 mm wide) following a primary discectomy procedure at a single level between L4 and S1. (5)

Rationale

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of the change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Lumbar Discectomy with Annular Closure Device

Clinical Context and Therapy Purpose

The purpose of an annular closure device after lumbar discectomy is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who are undergoing lumbar discectomy with large annular defects.

Interventions

The therapy being considered is a bone-anchored annular closure device. Annular closure devices are intended for use in large annular defects following discectomy.

Comparators

The comparator of interest is lumbar discectomy without use of an annular closure device.

Outcomes
The general outcomes of interest are symptoms, functional outcomes, health status measures, quality of life, treatment-related mortality, and treatment-related morbidity. Reherniation and reoperation following discectomy are specific outcomes of interest.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews
Miller et al. (2020) published a systematic review and meta-analysis of the Barricaid annular device in patients at high risk for lumbar disc reherniation. (6) Four trials (2 RCTs) were included in the meta-analysis (Table 1). Tables 2 and 3 summarize the characteristics and the results of the meta-analysis. The trial by Thomé et al. (2018) summarized below was the only trial to find a significant decrease in symptomatic reherniation or reoperation at 2 years. The other 3 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.

Table 1. Studies Included in Systematic Review and Meta-Analysis

Study	Miller et al. (2020) (6)
Barth et al. (2016) (7)	●
Cho et al. (2019) (8)	●
Thomé et al. (2018) (9)	●
Vukas et al. (2013) (10)	●

Table 2. Systematic Review and Meta-Analysis Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Miller et al. (2020) (6)	NR-2019	4	Post-discectomy patients with annular defect width of 6-10mm	801 (60-554)	Controlled studies (2 RCTs)	≥2 years

N: number; NR: not reported; RCT: randomized controlled trial.

Table 3. Systematic Review and Meta-Analysis Results

Study	Symptomatic reherniation	Reoperation
Miller et al. (2020) (6)		
Total N	754	797
Pooled effect (95% CI)	Risk ratio, 0.45 (0.31-0.66)	Risk ratio, 0.52 (0.34-0.80)
I^2 (p)	*0%* (<.0001)	*0%* (.003)
Range of N	60-507	60-550
Range of effect sizes (95% CI)	0.17 (0.02-1.3) to 0.49 (0.33-0.72)	0.17 (0.02-1.3) to 0.71 (0.20-2.47)

CI: confidence interval; N: number.

Randomized Controlled Trials

Two key RCTs have evaluated bone-anchored annular closure devices and are summarized in Tables 4 and 5.

Thomé et al. (2018) conducted an open-label RCT comparing lumbar discectomy alone or lumbar discectomy with annular closure. (9) A total of 554 patients who had failed nonsurgical treatment and had a disc height of at least 5 mm were randomized. Results at 2 years are summarized in Table 5. 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. (11) 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. (12) None of the investigators were blind to treatment assignment, and only patients at specific sites were blind.

Cho et al. (2019) published a smaller RCT conducted solely in Korea. (8) 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 (Table 5). The small sample size, large loss to follow-up (≤70% at 2-year follow-up), and unclear blinding limit the validity of this trial.

Table 4. Summary of Key RCT Characteristics

Study	Countries	Sites	Dates	Participants	Interventions	
					Active	**Comparator**
Thomé et al. (2018) (9)	EU	21	2010-2014	Pts 21 to 75 years of age with single-level disc herniation between L1 and S1, disc height ≥5 mm, and	Bone-anchored ACD + discectomy (n=276)	Discectomy alone (n=278)

				who failed ≥6 weeks of nonsurgical treatment.		
Cho et al. (2019) (8)	Korea	1	NR	Pts with sciatica unresponsive to ≥6 weeks of conservative treatment.	Bone-anchored ACD + discectomy (n=30)	Discectomy alone (n=30)

ACD: annular closure device; EU: European Union; NR: not reported; Pts: patients; RCT: randomized controlled trial.

Table 5. Summary of Key RCT Results

Study	Recurrent Herniation, %	Clinical Success, % [a]	Reoperation, %	Serious AE, %
Thomé et al. (2018) (9)	N=507	N=550	N=550	N=550
Annular closure	50	27	9	7.7
Control	70	18	16	16.2
MD (95% CI; p-value)	-20% (-12 to -28; p<.001)	9% (2 to 16; p=.02)	NR (p=.01)	-8.5% (p=.002)
NNT (95% CI)	<8	NR	<13	NR
Cho et al. (2019) (8)	N=41			
Annular closure	5			
Control	28.6			
Risk (p-value)	NR (p=.044)			

AE: adverse event; CI: confidence interval; MD: mean difference; NNT: number needed to treat; NR: not reported; RCT: randomized controlled trial.

[a] Clinical success was a composite endpoint of Oswestry Disability Index score improvement of ≥15 points, ≥20-point improvement in leg pain on VAS, maintenance of neurologic status, freedom from device- or procedure-related serious adverse events, and freedom from index level reoperation.

The purpose of the study limitations tables (see Tables 6 and 7) is to display notable limitations identified in each study.

Table 6. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Thomé et al. (2018) (9)	4. Enrolled populations do not reflect relevant diversity				

Cho et al. (2019) (8)	4. Enrolled populations do not reflect relevant diversity			1. Study focused on radiologic outcomes	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.
[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.
[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.
[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 7. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Complete-ness[d]	Power[e]	Statistical[f]
Thomé et al. (2018) (9)		1, 2. Participants not randomly allocated				
Cho et al. (2019) (8)		4. Blinding unclear		1. High-loss to follow-up or missing data	1. Power calculations not reported	

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.

[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

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 review identified 2 RCTs and 2 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, but the trial is limited by lack of blinding.

Summary of Evidence

For individuals who have a lumbar herniated disc 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 randomized controlled trials (RCT)s. Relevant outcomes are symptoms, functional outcomes, health status measures, quality of life, and treatment-related mortality and morbidity. Although a key RCT found beneficial effects in terms of reoperation and reherniation, the evidence is limited by a lack of blinding. In patients with lumbar radiculopathy with disc herniation who receive discectomy and an annular closure device, the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

International Society for the Advancement of Spine Surgery

In 2019, the International Society for the Advancement of Spine Surgery (ISASS) published a policy on the surgical treatment of lumbar disc herniation with radiculopathy. (4) This policy contained a review of available clinical evidence and concluded that discectomy (open, microtubular, or endoscopic) is a medically necessary procedure for the treatment of patients who do not respond to nonsurgical care or have severe and deteriorating symptoms. Per the policy, documentation requirements include confirmation of radiculopathy based on history/physical examination AND either the presence of disabling leg or backpain refractory to 6 weeks of conservative care or progressive neurologic deficit AND level appropriate documentation of nerve root compression on imaging and/or nerve conduction velocity/electromyogram. The ISASS also included specific recommendations for bone-anchored annular closure devices as follows:

- "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."

In 2025, ISASS reiterated that bone-anchored annular closure may be used to sustain the treatment benefits of discectomy in patients with symptomatic lumbar dis herniation with radiculopathy undergoing primary discectomy with large (≥6 mm wide) annular defects. (13)

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	22899
HCPCS Codes	C1889, C9757

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/01/2025	Document updated. The following change was made to Coverage: Revised Coverage statement to address only one device example; other examples were removed. Added reference 13; some updated and others removed.
05/15/2024	Document updated with literature review. Editorial Coverage change-added “following discectomy”-intent unchanged. References 4, 8-11 were added.
05/01/2023	Reviewed. No changes.
06/01/2022	Document updated with literature review. Coverage unchanged. Reference 14 added.

06/15/2021	New medical document. Use of annulus closure devices for annular repair (e.g., Barricaid®, InClose®, Xclose®, or Disc Annular Repair Technology [DART] System) is considered experimental, investigational and/or unproven.