MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Lumbar Microdiscectomy**
Policy Number	**7.01.98**
Category	**Technology Assessment**
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Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

I. Based on our criteria and assessment of the peer-reviewed literature, an initial, primary lumbar microdiscectomy (laminotomy, laminectomy or hemilaminectomy) has been medically proven to be effective and, therefore, is considered **medically appropriate** for radiculopathy/neurogenic claudication secondary to a herniated disc, synovial cyst or arachnoid cyst, or central/lateral/foraminal stenosis, when **ALL** the following criteria have been met:
   A. All other sources of pain have been excluded; and
   B. The patient has no unmanaged significant mental and/or behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, opioid or alcohol use disorders); and
   C. Subjective symptoms, including **BOTH** of the following:
      1. Clinically significant function limiting pain and/or symptoms on a daily basis (e.g., inability to perform household chores, prolonged standing, or essential job functions); and
      2. Pain, cramping, weakness, or tingling in the lower back, buttock(s), and legs brought about by walking or positions that cause thecal sac or nerve root compression (e.g., standing, extension) and **EITHER** of the following:
         a. Symptoms worsen with standing and/or walking; or
         b. Symptoms are alleviated with sitting and/or forward flexion; or
   D. Objective physical examination findings concordant with recent (within six (6) months) MRI/CT; and
   E. Significant level of pain on a daily basis, defined as either of the following:
         a. Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) greater than or equal to seven (7); or
         b. severe, disabling, crippling, or incapacitating pain; and/or
   F. Persistent radiating pain into the buttock(s) and/or lower extremity(ies) on a daily basis that has a documented negative impact on activities of daily living despite optimal conservative therapy; and
   G. Objective physical findings, including **EITHER** of the following, are present:
      1. Nerve root tension sign, including any of the following:
         a. positive straight leg raise; or
         b. crossed straight leg raise; or

c. femoral stretch test;
2. Neurologic deficit, including any of the following:
   a. Dermatomal sensory deficit; or
   b. Functionally limiting motor weakness (e.g., foot drop, quadriceps weakness); or
   c. Reflex changes.

H. Recent (within six (6) months) MRI/CT identifies nerve root impingement and/or thecal sac impingement that correlates with patient symptoms and physical findings and is caused by at least **ONE (1) OR MORE** of the following:
   1. herniated disc(s); or
   2. synovial cyst/arachnoid cyst; or
   3. central/lateral/foraminal stenosis;

I. The patient has experienced less than clinically meaningful improvement with at least **TWO (2)** of the following, unless contraindicated:
   1. prescription strength analgesics, steroids, and/or NSAIDS for six (6) weeks; and/or
   2. provider-directed exercise program prescribed by a physical therapist, chiropractic provider, or osteopathic or allopathic physician for six (6) weeks; and/or
   3. epidural steroid injections/selective nerve root block(s).

II. Based on our criteria and assessment of the peer-reviewed literature, a repeat lumbar microdiscectomy (laminotomy or laminectomy) at the same level has medically been proven to be effective and, therefore, is considered **medically appropriate** for radiculopathy/neurogenic claudication secondary to a herniated disc, synovial cyst or arachnoid cyst, or central/lateral/foraminal stenosis, when **ALL** the following criteria have been met:

A. Recent (within six (6) months) post-operative MRI /CT confirms evidence of neural structure compression at the requested level(s) that is concordant with patient symptoms and physical examination findings and is caused by **ONE (1) OR MORE** of the following:
   1. Herniated Disc (retained disc material or a recurrent disc herniation); and/or
   2. Synovial cyst or arachnoid cyst; and/or
   3. Central/lateral/foraminal stenosis

B. Greater than 12 weeks have elapsed since initial lumbar disc decompression surgery; and

C. Subjective symptoms including **BOTH** of the following:
   1. Clinically significant function limiting pain and/or symptoms on a daily basis (e.g., inability to perform household chores, prolonged standing, or essential job functions); and
   2. Pain, cramping, weakness, or tingling in the lower back, buttock(s), and legs brought about by walking or positions that cause thecal sac or nerve root compression (e.g., standing, extension) and **EITHER** of the following:
      a. Symptoms worsen with standing and/or walking; or
      b. Symptoms are alleviated with sitting and/or forward flexion; and/or

D. The patient experienced initial relief of symptoms following previous disc decompression procedure (within six (6) months) at the same level, unless post-operative imaging demonstrates persistent significant neurologic compression at the surgical level; and

E. All other sources of pain have been excluded; and

F. The patient has no unmanaged significant mental and/or behavioral health disorders (e.g., major depressive disorder, chronic pain syndrome, secondary gain, opioid or alcohol use disorders); and

G. Significant level of pain on a daily basis, defined as either of the following:
   1. Visual Analog Scale (VAS)/Numeric Rating Scale (NRS) greater than or equal to seven (7); or
   2. severe, disabling, crippling, or incapacitating pain; and/or

H. Persistent radiating pain into the buttock(s) and/or lower extremity(ies) on a daily basis that has a documented negative impact on activities of daily living despite optimal conservative therapy; and

I. Objective physical examination findings concordant with recent (within six (6) months) MRI/CT; and

J. Objective physical examination findings including **EITHER** of the following:
   1. Nerve root tension sign, including during **ANY** of the following:

a. positive straight leg raise; or
b. crossed straight leg raise; or
c. femoral stretch test; and/or

2. Neurologic deficit, including **ANY** of the following:
   a. Dermatomal sensory deficit; or
   b. Functionally limiting motor weakness (e.g., foot drop, quadriceps weakness); or
   c. Reflex changes; **AND**

K. Less than clinically meaningful improvement with at least TWO of the following, unless contraindicated:
1. prescription strength analgesics, steroids, and/or NSAIDS for six (6) weeks; and/or
2. provider-directed exercise program prescribed by a physical therapist, chiropractic provider, or osteopathic or allopathic physician for six (6) weeks; and/or
3. epidural steroid injections/selective nerve root block(s).

III. Based on our criteria and assessment of the peer-reviewed literature, the performance of microdiscectomy (laminotomy, laminectomy or hemilaminectomy) with laser technique is considered **not medically necessary**.

IV. Based on our criteria and assessment of the peer-reviewed literature, initial and repeat lumbar microdiscectomy (laminotomy, laminectomy or hemilaminectomy) is considered **not medically necessary** for **ANY** of the following sole indications:
A. Subjective symptoms and objective physical examination findings are not concordant with imaging; and/or
B. The patient has predominant lower back pain associated with disc degeneration, with or without annular tears in the absence of a disc herniation; and/or
C. The patient is asymptomatic with a normal physical examination, regardless of the size of the disc herniation; and/or
D. The patient's imaging shows disc bulge with no neural impingement or cord compression; and/or
E. The patient's discography is concordant; and/or
F. The patient's magnetic resonance (MR) spectroscopy results; and/or
G. The patient has experienced only isolated axial lower back pain in the presence of disc herniation.

V. Based upon our criteria and assessment of the peer-reviewed literature, the use of an annular (annulus) fibrosis repair/closure device following spinal surgery, including, but not limited to, use of the Barricaid Annular Closure Device (ACD), has not been medically proven to be effective and, therefore, is considered **investigational**.

Refer to Corporate Medical Policy #7.01.16 Automated Percutaneous Discectomy and Image-Guided, Minimally Invasive Decompression

Refer to Corporate Medical Policy #7.01.62 Intervertebral Disc Decompression: Laser (Laser Discectomy) and Radiofrequency Coblation (Disc Nucleoplasty) Techniques

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services.

POLICY GUIDELINES

I. Acceptable imaging modalities are CT scan, MRI, and myelogram. Imaging must be performed and read by an independent radiologist. If discrepancies should arise in the interpretation of the imaging, interpretations by the radiologist will supersede all other interpretations. Discography results will not be used as a determining factor of medical necessity for any requested procedures. Use is not endorsed.

II. Clinically meaningful improvement is defined as global assessment showing at least 50% improvement.

III. URGENT/EMERGENT CONDITIONS: All patients being evaluated for spine surgery should be screened for indications of a medical condition that requires urgent/emergent treatment. The presence of such indications/conditions warrants definitive surgical treatment. Confirmatory advanced imaging studies, such as a CT scan or MRI, are required. Provider-directed, non-surgical management and absence of unmanaged significant mental and/or behavioral health disorders are **NOT** required. Urgent/emergent conditions for lumbar microdiscectomy and excision of extradural lesion other than neoplasm include **ANY** of the following:

A. cauda equina syndrome (CES); or
B. documentation of progressive neurological deficit on two separate physical examinations;
C. **ANY** of the following due to a neurocompressive pathology
    i. Motor weakness of grade 3/5 or less of specified muscle(s); or
    ii. Rapidly progressive symptoms of motor loss; or
    iii. Bowel incontinence; or
    iv. Bladder incontinence/retention
D. epidural hematoma; or
E. infection (e.g., discitis, epidural abscess, osteomyelitis); or
F. primary or metastatic neoplastic disease-causing pathologic fracture, cord compression or instability; or
G. documentation of severe debilitating pain and/or dysfunction to the point of being incapacitated.

DESCRIPTION

The procedure to relieve the pressure on a spinal nerve resulting from a herniated lumbar disc is referred to as a microdiscectomy. Microscopic lumbar discectomy surgery involves the use of a microscope to improve surgical lighting and vision, making the herniated lumbar disc surgery more precise and accurate. Specially designed surgical instruments are then used during microscopic discectomy, to remove bone spurs and the lamina on the side of the approach. This is referred to as a laminectomy. The disc is then exposed by gently retracting the nerves, and the fragments of herniated disc are dissected free and carefully removed. Microdiscectomies can be performed using three main techniques:

I. Mini-open: This is similar to an open discectomy, but the surgeon uses advanced technology to view the spine through smaller incisions.
II. Tubular: The surgeon inserts a tube through a small incision. This tube is gently pushed through the back muscles until it reaches the spine, and then a series of expanding tubes is inserted, one around the other. These tubes gradually open up (or dilate) the area where the surgery will be performed. The surgeon then uses specially-designed instruments to remove part of the disc through this tube.
III. Endoscopic: A tiny video camera (called an endoscope) is inserted through a tube, to enable the surgeon to see the spine and remove disc material with miniaturized instruments.

The Barricaid ACD (Intrinsic Therapeutics, Woburn, MA) received FDA pre-market approval in February 2019. It is implanted during a lumbar discectomy procedure, to act as a barrier to block the annular defect and reduce reherniation and reoperation. The device is a permanent implant, consisting of titanium and a flexible woven polymer fabric mesh, and is intended to close a large annular defect following a limited, single-level, discectomy procedure between L4 and S1.

RATIONALE

Overall, the literature suggests that lumbar discectomy provides effective clinical benefit in carefully selected patients with sciatica. There is strong evidence in favor of microdiscectomy surgery over conservative treatment at short-term follow-up. The comparative evidence on lumbar discectomy versus conservative care consists of a small number of randomized, controlled trials (RCTs) and non-randomized comparative studies. The RCT evidence is limited by a lack of high-quality trials. In most, a high percentage of patients in the conservative care group crossed over to receive surgery. This high degree of contamination reduced the ability to detect a difference when assessed by intention-to-treat (ITT) analysis. Analysis by treatment received was also flawed because of the potential noncomparability of groups, resulting from the high volume of crossover. Despite the methodologic limitations of the evidence, the RCTs are consistent in demonstrating a probable short-term benefit for surgery and a more rapid resolution of pain and disability. For the ITT analyses, there were small differences in favor of surgery, which sometimes were statistically significant and at other times, were not. In contrast, on analysis by treatment received and in the non-randomized comparative studies, there were larger differences in favor of surgery that exceeded the threshold for clinical significance. At one year or longer, outcomes from surgery and conservative care appear to be equivalent.

In 2015, Lewis and colleagues published a network meta-analysis comparing 21 different strategies for treatment of sciatica. Reviewers included a total of 122 comparative studies, 90 of which were RCTs. For disc surgery, eight studies compared surgery with conservative care (three RCTs, one quasi-RCT, four cohort studies), and 34 studies compared

discectomy with alternative treatments, including other surgical variations. For the main outcome (overall recovery), surgery was better than exercise therapy, traction, and percutaneous discectomy. However, for the outcome of pain, disc surgery was not found to be better than alternative treatments.

A systematic review based on a Cochrane review was published by Jacobs, et al. in 2011. Reviewers evaluated surgery and conservative management of sciatica due to lumbar herniated disc. They included five (5) RCTs, four (4) of which are discussed below, with the additional trial being a 1983 trial excluded from this review. Reviewers assigned a low risk of bias to two of the four trials: the randomized Spine Patient Outcomes Research Trial (SPORT) and the Leiden-The Hague Spine Intervention Prognostic Study. They determined that pooling of the results was not appropriate, due to differences in study methodologies, so a qualitative synthesis of the data was performed. Reviewers concluded that surgery was likely to lead to better short-term control of leg pain, but that the overall quality of the body of evidence for this outcome was low. No differences were demonstrated between surgical and conservative care outcomes at one year and beyond.

Chou et al. (2009) published a systematic review of the evidence for efficacy of different surgical procedures for back pain, in conjunction with development of clinical guidelines for the American Pain Society. For the comparison of discectomy with nonsurgical care, four (4) studies were included, three (3) of which are reviewed below. Studies were not pooled. Reviewers found that discectomy, performed either by open surgery or microdiscectomy, had superior outcomes for pain and disability at up to three months, but no definite benefits at longer time points.

Weinstein et al. (2006) reported on SPORT, a moderately-large trial that compared discectomy to non-operative care in patients with lumbar disc herniation and included both a randomized and a non-randomized component. The RCT included 501 patients randomized to discectomy or to usual care. Discectomy was performed by the open technique, and, in some cases, the medial border of the superior facet joint was removed. Crossover was allowed during the trial; 107 of the 245 patients assigned to usual care underwent surgery, and 140 of the 245 patients assigned to surgery underwent surgery. The main outcomes were changes from baseline in the bodily pain and physical function subscales of the SF-36, and the modified Oswestry Disability Index (ODI) measured at time points up to two years. Secondary outcomes included self-reported improvement, work status, satisfaction with care, and a symptom severity measure (Sciatica Bothersomeness Index). For the primary outcomes evaluated using ITT analysis, improvements in ODI scores were superior for the surgery group at three months, but, at the one- and two-year follow-ups, there were no significant group differences on either primary outcome. For secondary outcomes, there were significant improvements for the surgery group on the Sciatica Bothersomeness Index at all time points, and satisfaction with care was superior for the surgery group at three (3) months, but not at longer time points. A secondary analysis was performed on a treatment-received basis, and this analysis showed significantly greater improvements for the surgery group at all time points. The estimated treatment effects for the SF-36 bodily pain and physical function subscales were 15.0 and 17.5, respectively, on a 0-to-100 scale. The estimated change in the ODI score was -15.0 on a 0 to 100 scale.

Thome and colleagues (2018) conducted a randomized, controlled trial at 21 European centers, to determine whether use of a bone-anchored ACD, in addition to lumbar microdiscectomy, resulted in lower reherniation and reoperation rates and increased overall success, compared to lumbar microdiscectomy alone. Enrolled patients were 21 to 75 years of age, with imaging confirmation of single-level disc herniation between L1 and S1, disc height 5mm or greater, who had attempted nonsurgical treatment for six (6) weeks or more. The modified ITT population used for efficacy analyses included 550 patients (272 ACD and 278 controls). Implantation of the ACD was unsuccessful in five patients; therefore, the as-treated population, used for safety analyses, included 267 patients in the ACD group and 283 controls. Both primary endpoints were met, with recurrent herniation occurring in 50% of the ACD group and 70% of the control group. Symptomatic reherniation was lower in the ACD group (12% versus 25%). There were 29 index-level, any-cause reoperations in 24 patients who received an ACD, and 61 reoperations in 45 control patients (9% versus 16%). There were no differences in all-cause serious adverse events when ACD was compared to controls. Three-year outcomes demonstrated that lumbar discectomies using ACD resulted in fewer symptomatic reherniations than discectomies without ACD implantation (15% vs. 30%), as well as fewer reoperations (11% versus 19%). Disability and quality of life scores demonstrated modest improvement in the ACD group over the control group at three years (Kienzler et al. 2019). Four-year reoperation rates were 14.4% with ACD and 21.1% with controls (Nanda et al. 2019). The study was funded by Intrinsic Therapeutics.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
62380	Endoscopic decompression of spinal cord, nerve root(s), including laminotomy, partial facetectomy, foraminotomy, discectomy, and/or excision of herniated intervertebral disc, 1 interspace, lumbar
63030	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; 1 interspace, lumbar
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar [when specified as lumbar]
63042	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, re-exploration, single interspace; lumbar
63044	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, re-exploration, single interspace; each additional lumbar interspace
63056	Transpedicular approach with decompression of spinal cord, equine and/or nerve root(s) (e.g., herniated intervertebral disc), single segment; lumbar (including transfacet, or lateral extraforaminal approach) (e.g., far lateral herniated intervertebral disc)
63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (e.g., herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar [when specified as lumbar]
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar
63272	Laminectomy for excision of intraspinal lesion other than neoplasm, intradural; lumbar
63277	Laminectomy for biopsy/excision of intraspinal neoplasm; extradural, lumbar

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HCPCS Codes

Code	Description
C9757 **(E/I)**	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
S2350	Discectomy, anterior with decompression of spinal cord and/or nerve root(s); including osteophytectomy; lumbar, single interspace
S2351	Discectomy, anterior with decompression of spinal cord and/or nerve root(s); including osteophytectomy; lumbar, each additional interspace

ICD10 Codes

Code	Description
D16.6	Benign neoplasm of vertebral column
D32.1	Benign neoplasm of spinal meninges
D33.4	Benign neoplasm of spinal cord
M51.06	Intervertebral disc disorders with myelopathy, lumbar region
M51.16-M51.17	Intervertebral disc disorders with radiculopathy, lumbar/lumbosacral regions
M51.26-M51.27	Other intervertebral disc displacement, lumbar/lumbosacral regions
M51.36-M51.37	Other intervertebral disc degeneration, lumbar/lumbosacral regions
M51.46-M51.47	Schmorl's nodes, lumbar/lumbosacral regions
M51.86-M51.87	Other intervertebral disc disorders, lumbar/lumbosacral regions
M54.16-M54.17	Radiculopathy, lumbar/lumbosacral regions

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*Key Article

KEY WORDS

Hemilaminectomy, laminectomy, laminotomy, microdiscectomy, endoscopic decompression

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based upon review, lumbar microdiscectomy is not specifically addressed in a National or Local Medicare coverage determination or policy.