EPIDUROSCOPY, EPIDURAL LYSIS OF ADHESIONS AND FUNCTIONAL ANESTHETIC DISCOGRAPHY

Policy Number: PAIN 004.18 T2  
Effective Date: January 1, 2017

Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>INSTRUCTIONS FOR USE</td>
<td>1</td>
</tr>
<tr>
<td>APPLICABLE LINES OF BUSINESS/PRODUCTS</td>
<td>2</td>
</tr>
<tr>
<td>BENEFIT CONSIDERATIONS</td>
<td>2</td>
</tr>
<tr>
<td>NON-COVERAGE RATIONALE</td>
<td>3</td>
</tr>
<tr>
<td>APPLICABLE CODES</td>
<td>3</td>
</tr>
<tr>
<td>DESCRIPTION OF SERVICES</td>
<td>3</td>
</tr>
<tr>
<td>CLINICAL EVIDENCE</td>
<td>3</td>
</tr>
<tr>
<td>U.S. FOOD AND DRUG ADMINISTRATION</td>
<td>6</td>
</tr>
<tr>
<td>REFERENCES</td>
<td>7</td>
</tr>
<tr>
<td>POLICY HISTORY/REVISION INFORMATION</td>
<td>8</td>
</tr>
</tbody>
</table>

INSTRUCTIONS FOR USE

This Clinical Policy provides assistance in interpreting Oxford benefit plans. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage members. Oxford reserves the right, in its sole discretion, to modify its policies as necessary. This Clinical Policy is provided for informational purposes. It does not constitute medical advice. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Clinical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Clinical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Clinical Policy. Other Policies may apply.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

APPLICABLE LINES OF BUSINESS/PRODUCTS

This policy applies to Oxford Commercial plan membership.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.
**NON-COVERAGE RATIONALE**

**Epiduroscopy (including spinal myeloscopy) is unproven and not medically necessary for the diagnosis of back pain.**

There is insufficient evidence to conclude that epiduroscopy can improve patient management or disease outcomes. The available studies primarily evaluated the feasibility of the procedure and the ability to visualize normal and pathological structures with an epiduroscope. None of the studies systematically evaluated the accuracy of epiduroscopy for diagnosis of causes of back pain and neurological signs.

**Percutaneous and endoscopic epidural lysis of adhesions is unproven and not medically necessary for the treatment of back pain.**

There is insufficient evidence to conclude that epidural lysis of adhesions can provide sustained reduction in chronic back pain in patients with a presumptive diagnosis of epidural adhesions. No published studies have evaluated this procedure relative to open surgical procedures for chronic back pain. Further validation with larger study populations and long term follow-up is needed to verify the effectiveness of epidural adhesiolysis in the treatment of back pain.

**Functional anesthetic discography (FAD) is unproven and not medically necessary for the diagnosis of back pain.**

Although researchers are presently investigating the use of FAD for diagnosing discogenic pain, there is insufficient evidence at this time to draw conclusions.

**APPLICABLE CODES**

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies may apply.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>62263</td>
<td>Percutaneous lysis of epidural adhesions using solution injection (e.g., hypertonic saline, enzyme) or mechanical means (e.g., catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days</td>
</tr>
<tr>
<td>62264</td>
<td>Percutaneous lysis of epidural adhesions using solution injection (e.g., hypertonic saline, enzyme) or mechanical means (e.g., catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 1 day</td>
</tr>
<tr>
<td>62292</td>
<td>Injection procedure for chemonucleolysis, including diskography, intervertebral disk, single or multiple levels, lumbar</td>
</tr>
<tr>
<td>64999</td>
<td>Unlisted procedure, nervous system</td>
</tr>
</tbody>
</table>

**Coding Clarification:** Functional anesthetic discography should be billed with CPT code 64999.

**DESCRIPTION OF SERVICES**

Epiduroscopy involves the percutaneous insertion of a fiberoptic endoscope to view the epidural space that is inside the spinal canal. Epiduroscopy has been proposed as a technique to identify pathological structures such as epidural adhesions, fibrosis, and scars. This is also done with a myeloscope which is a video-guided catheter system and introducer system.

Epidural lysis of adhesions (adhesiolysis, percutaneous, epidural neuroplasty, epidurolysis) is a minimally invasive procedure for patients who have epidural adhesions that are thought to cause chronic low back pain. The procedure is often performed using local anesthesia and a mild sedative, so the patient is able to communicate with the surgeon about the source of the pain. The surgeon injects normal saline to distend and decompress the epidural space and mechanical manipulations of a fiberoptic endoscope to cause direct disruption of fibrosis, scar tissue, or adhesions. Percutaneous epidural adhesiolysis (also known as the Racz procedure) can also be performed. This procedure uses a needle to enter the epidural space at the level of the spinal column where adhesions are suspected. Nonionic contrast medium is introduced, and a lumbar epidurogram is obtained. Epidural fibrosis is localized by the filling defects during contrast flow into the nerve root. A flexible catheter is placed through the needle into the site of the defect. (Hayes, 2015)
Functional Anesthetic Discography (FAD) is a diagnostic procedure that involves injecting an anesthetic agent directly into a spinal disc via a catheter system. Once the catheter is inserted into the disc nucleus, the patient tries to recreate the back pain by performing activities such as sitting, walking or bending. If pain is produced, an anesthetic agent is injected and the patient again attempts to recreate the back pain. The amount of pain is then compared and used to confirm the level of disc involvement and determine additional treatment options.

**CLINICAL EVIDENCE**

**Epiduroscopy**

Results of earlier feasibility/observational studies suggest that epiduroscopy can aid in the visualization of the anatomy and pathology of spinal structures; in particular, the cauda equina and epidural space. However, none of those studies evaluated the impact of epiduroscopy on clinical management or patient outcomes.

A prospective observational study by Bosscher and Heavner (2014) evaluated the significance of diagnostic markers obtained through epiduroscopy by evaluating the accuracy of outcome prediction after treatment of epidural pathology using epiduroscopy. Of the 150 patients who underwent epiduroscopy in the year 2008 at a U.S. hospital, 139 were available for evaluation at 1 month. A prediction of outcome was made in 114 of 139 patients (82%). This prediction was correct in 89 of the 114 patients (accuracy of 78%). The sensitivity and specificity of epiduroscopy with respect to the prediction of outcome were 75% and 82%, respectively. The sensitivity and specificity of epiduroscopy in the diagnosis of epidural pathology were 91% and 39%, respectively. The authors concluded that lumbosacral epiduroscopy predicts outcome of treatment accurately in the majority of patients. This suggests that information obtained through epiduroscopy may carry significant diagnostic and prognostic value.

Two studies concluded that epiduroscopy could identify the cause of pain and other neurological signs in some patients who had been either undiagnosed or incorrectly diagnosed by radiography or magnetic resonance imaging (MRI). Uchiyama et al. (1998) reported that in 4 out of 18 patients, epiduroscopy identified a spinal cord mass that had been diagnosed radiographically as a cyst or herniation of the spinal cord. In another study, Geurts et al. (2002) reported that epiduroscopy outperformed MRI in 8 out of 20 patients with chronic sciatica with or without FBSS. In this study, MRI findings agreed with epiduroscopy observations in 11 patients, while epiduroscopy identified an adhesion on the nerve root in 8 patients in whom MRI detected no abnormalities of the spinal structures. However, this study was very small and no conclusions regarding the relative accuracy of epiduroscopy versus MRI for diagnosis of spinal cord or epidural pathology can be drawn. In this study, patients with adhesions were treated with a combination of hyaluronidase, steroid, and clonidine; this therapy appeared to provide significant pain relief in some patients, although the effect diminished within 12 months. These results were similar to those reported earlier by Richardson et al. (2001), who described reductions in pain and disability in patients with adhesions who were treated with steroids and clonidine during epiduroscopy examinations.

Igarashi et al. (2004) conducted a study of 58 patients with degenerative lumbar spinal stenosis who were placed into 2 groups, a monosegmental or multisegmental group, based on leg symptoms. All patients underwent epiduroscopy with epidural injection of steroid or local anesthetic. The findings of epiduroscopy corresponded to the symptoms, and the study results demonstrated positive effects of epiduroscopy on low back pain for up to 1 year in both groups.

There is insufficient evidence in the published medical literature to support the use of epiduroscopy as a diagnostic procedure. Further studies, preferably randomized controlled trials, are necessary to evaluate the safety and efficacy of epiduroscopy.

**Professional Societies**

**American College of Occupational and Environmental Medicine (ACOEM)**

In the Guideline Summary for Low Back Pain (LBP), the ACOEM does not recommend myeloscopy for diagnosing acute, subacute or chronic LBP, spinal stenosis, radicular pain syndromes, or postsurgical back pain problems (2011).

**Epidural Lysis of Adhesions**

Lee et al. (2015) conducted an evidence based literature review of clinical trials, observational studies, retrospective studies, animal studies, review articles, case series and reports, and guidelines between 1970 and 2013. They concluded that the evidence surrounding lysis of adhesions is still controversial, with no randomized studies comparing percutaneous and endoscopic lysis of adhesions, the anatomical relationship between scar tissue and pain symptoms is not clear, and larger, more methodologically sound studies that compare adhesiolysis to placebo, and to other treatments are needed.

Donato et al. (2011) reported a 48-month follow-up from a prospective case series of 234 individuals with chronic low back pain. In addition to mechanical removal of adherences, targeted ozone, hyaluronidase and ciprofloxacin were applied. Efficacy was prospectively evaluated by an independent investigator at 1 week and 3, 6, 12, 24, 36, and 48 months.
months. Significant improvements in VAS and ODI scores were reported throughout the 48 month follow-up. Although positive outcomes were reported, the study was limited by the lack of a control group and a large number of participants lost to follow-up at 48 months.

A randomized, double-blind trial was conducted by Gerdesmeyer et al. (2013) to analyze the clinical efficacy of percutaneous epidural lysis of adhesions in chronic radicular pain. Out of 381 patients with chronic radicular pain lasting longer than 4 months which failed to respond to conservative treatments, 90 individuals were enrolled. They were randomly assigned to receive either percutaneous neurolysis or placebo with concealed allocation in permuted blocks of 4 to 8, stratified by treatment center. The primary outcome measure was the differences in percent change of Oswestry Disability Index (ODI) scores 3 months after intervention. Secondary outcome measures were differences in percent change of ODI scores and Visual Analog Scale. The ODI and VAS scores as well as the success rates for ODI vs VAS were significantly better 3, 6, and 12 months in the lysis group vs the control group. The ODI in the lysis group improved from 55.3 ± 11.6 to 26.4 ± 10.8 after 3 months. The placebo group improved from 55.4 ± 11.5 to 41.8 ± 14.6 VAS improved from 6.7 ± 1.1 to 2.9 ± 1.9 in the active group and from 6.7 ± 1.1 to 4.8 ± 2.2 after placebo. Twelve month follow-up shows further improvement, the differences remain significant. A limitation of the study noted by the authors is that specific effects of single treatment components cannot be specified because there was no imaging examination after treatment.

A randomized controlled trial by Manchikanti et al. (2009a) compared the effectiveness of percutaneous epidural adhesiolysis with epidural steroid injections in post-surgical patients with chronic low back and lower extremity pain. There were 60 patients in each group. Outcomes were measured using the Numeric Rating Scale (NRS), the Oswestry Disability Index 2.0 (ODI), employment status, and opioid intake. Follow-up occurred at 3, 6, and 12 months post treatment. The average procedures performed were 3.5 with the adhesiolysis group having relief for 42 out of 52 weeks. This resulted in significant pain relief (> 50%) and functional status improvement in 73% of the patients. The epidural steroid group average 2.2 injections and had pain relief for 13 out of 52 weeks with only 12% of patients reporting pain relief and improvement in functional status. A total of 43 patients in the epidural steroid group were lost to follow-up compared with 2 patients from the adhesiolysis group. The authors concluded that percutaneous epidural adhesiolysis is effective in patients with post lumbar surgery syndrome. The study reports preliminary results and is limited by lack of subjective end points and the significant number of patients lost to follow-up in the epidural steroid group limits ability to compare the 2 procedures.

Another randomized controlled trial by Manchikanti et al. (2009b) compared the effectiveness of percutaneous epidural adhesiolysis with fluoroscopically directed caudal epidural injections in patients with chronic low back and lower extremity pain with lumbar central spinal stenosis. There were 25 patients in each group. Outcomes were measured using the Numeric Rating Scale (NRS), the Oswestry Disability Index 2.0 (ODI), employment status, and opioid intake. Follow-up occurred at 3, 6, and 12 months post treatment. Significant pain relief was described as 50% or more, whereas significant improvement in the disability score was defined as a reduction of 40% or more. All patients underwent similar procedures with the exception of 2 main differences. Group I had the catheter introduced up to S3 and injection of non-saline while Group II had targeted placement to the level of the defect and injection of 10% sodium chloride solution. The study showed pain relief (> 50%) in 76% of the adhesiolysis group patients at one year follow-up compared to 4% in the control group. A total of 18 patients (72%) in the control group were lost to follow-up. The authors concluded that percutaneous epidural adhesiolysis is effective in patients with lumbar spinal stenosis. The study reports preliminary results and is limited by small sample size, lack of comparison to a placebo group or conservative treatment, subjective outcomes and inability to generalize across all populations.

A research paper by Manchikanti et al. (2013) evaluated the effectiveness of percutaneous epidural adhesiolysis in 70 patients with chronic low back pain and lower extremity pain with lumbar central spinal stenosis. All patients received percutaneous adhesiolysis with placement of a Racz catheter, followed by an injection of 5 mL of 2% preservative-free lidocaine. During recovery, each patient also received 6 mL of 10% hypertonic sodium chloride solution, 6 mg of nonparticulate betamethasone, followed by an injection of 1 mL of sodium chloride solution. The authors report that significant pain relief and functional status improvement of 50% or more was seen in 71% of patients at the end of 2 years. However the limitations of this study include lack of a control group and a prospective design.

Veihelmann et al. (2006) conducted a study of 99 patients with chronic lower back pain and sciatica to investigate whether minimally invasive techniques for adhesiolysis are superior to conservative treatment with physiotherapy. Patients were randomly assigned into either a group with physiotherapy (n=52) or a group undergoing epidural neuroplasty (n=47). Patients were assessed before and 3, 6, and 12 months after treatment by a blinded investigator. After 3 months, the visual analog scale (VAS) score for back and leg pain, was significantly reduced in the epidural neuroplasty group, and the need for pain medication was reduced in both groups. Furthermore, the VAS for back and leg pain as well as the Oswestry disability score were significantly reduced until 12 months after the procedure in contrast to the group that received conservative treatment. The authors concluded that epidural neuroplasty results in significant alleviation of pain and functional disability in patients with chronic low back pain and sciatica based on disc protrusion/prolapse or failed back surgery on a short-term basis as well as at 12 months of follow-up. However, a
serious shortcoming of this study is that 13 (25%) of the patients who underwent physical therapy were not available for follow-up at 3 months due to refusal of re-evaluation (n=10) or treatment with open discectomy (n=3). Pain and disability were assessed at 6 and 12 months in patients who remained in the study; however, it is difficult to interpret these data since 12 (23%) of the patients who underwent physical therapy chose to undergo epidural adhesiolysis and they were also excluded from the study. For patients who underwent adhesiolysis as their initial treatment, improvements were relatively stable over time. Specifically, mean disability score was 54% better at 3 months versus 50% better at 12 months and mean leg and back pain scores were 67% to 68% better at 3 months versus 61% better at 12 months. Parallel improvements were observed in a measure of analgesic use but the statistical significance of change in this outcome measure was not reported.

Manchikanti et al. (2004) conducted another study on 75 patients who were randomized into 3 treatment groups. Three types of interventions were included, with Group I serving as control with catheterization without adhesiolysis, followed by injection of local anesthetic, normal saline, and steroid. Group II consisted of catheterization and adhesiolysis, followed by injection of local anesthetic, normal saline, and steroid. Group III consisted of adhesiolysis followed by injection of local anesthetic, hypertonic saline, and steroid. Visual Analogue Scale pain scores, Oswestry Disability Index, work status, opioid intake, range of motion measurement, and P-3 was utilized to measure outcomes. Significant pain relief was defined as average relief of 50% or greater. Significant improvement was seen in patients in Group II and III, at 3 months, 6 months, and 12 months, compared to baseline measurements, as well as compared to Group I without adhesiolysis. Seventy-two percent of patients in Group III, 60% of patients in Group II, compared to 0% in Group I showed significant improvement at 12-month follow-up. The average number of treatments was 2.1 to 2.8 to obtain the improvements reported. Duration of improvement after the initial treatment was 2.8 ± 1.49 months in Group II and 3.8 ± 3.37 months in Group III. The authors concluded that percutaneous adhesiolysis, with or without hypertonic saline neurolysis, is an effective treatment for chronic low back pain.

Heavner et al. (1999) performed an early randomized controlled trial that evaluated 4 variations of percutaneous epidural adhesiolysis. For this study, 59 patients were randomized to and completed adhesiolysis with or without hypertonic saline and with or without hyaluronidase. All treatment groups had similar outcomes, both at discharge and at 12 months follow-up. For instance, pain scores at discharge were decreased at least 3 points on a 10-point scale in 80% to 88% of patients in every treatment group; however, approximately 70% of patients underwent 1 or more additional treatments such as repeat adhesiolysis, lumbar facet injection, hypogastric plexus blocks, muscle injections, nerve root injections, or spinal cord stimulation. The mean time between adhesiolysis and the first additional treatment was approximately 2.3 months for all groups. This study did not include a conservatively treated control group and there was a financial conflict-of-interest for one of the investigators.

A systematic review by Epter et al. (2009) which included the 3 studies above (Veihelmann et al., 2006; Manchikanti et al., 2004; Heavner et al., 1999) evaluated the effectiveness of percutaneous adhesiolysis in managing chronic low back and lower extremity pain due to post lumbar surgery syndrome. Of the 263 studies identified, 13 were considered for inclusion with only 7 meeting the inclusion criteria. The primary outcome measure was pain relief (short-term relief of at least 6 months and long-term relief of more than 6 months). Secondary outcome measures were improvement in functional status, psychological status, return to work, and change in opioid intake. Of the 3 randomized trials evaluating percutaneous adhesiolysis, all showed positive results for short and long-term relief. Of the 4 observational studies, 3 studies showed positive results for both short- and long-term improvement, whereas one study was positive for short-term and negative for long-term relief. The authors concluded that percutaneous adhesiolysis is an effective treatment, it is superior to epidural steroid injections, and it is a safe procedure for failed back surgery syndrome when performed appropriately. It is unclear why evidence was not included in the review during the timeframe of 1999 and 2009.

In a literature review by Racz et al. (2008), primary sources of information included: (1) 2 systematic literature reviews that include literature published through September 2006; (2) expert opinions; and (3) peer-reviewed publications from September 2006 to January 2008. The focus was on percutaneous entry using catheters via the sacral hiatus to treat pain in the lumbosacral region. The evidence is strong for short-term efficacy (3 months) and moderate for long-term efficacy (greater than 3 months). Complications do occur, but there is limited literature that documents incidence. The authors concluded that the cumulative evidence through January 2008 showed that percutaneous adhesiolysis with targeted drug delivery is an effective treatment for LBP and/or radiculopathy.

The quality of the overall body of evidence is low the studies are generally small observational studies that lack sufficient statistical power. Another limitation of the evidence is the heterogeneous character of the patient populations, treatment methods, co-administration of drugs, postoperative evaluation times, and outcome measures. Additional well-designed, larger studies are needed to determine the optimal technique and durability of treatment effect, and to determine which patients would derive the most benefit from this procedure.
Professional Societies
National Institute for Health and Care Excellence (NICE)
A 2010 assessment concluded that “current evidence on therapeutic endoscopic division of epidural adhesions is limited to some evidence of short-term efficacy, and there are significant safety concerns. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and audit or research.”

American College of Occupational and Environmental Medicine (ACOEM)
The ACOEM practice guidelines on Low Back Disorders, (2011) state that adhesiolysis is not recommended to treat acute, subacute or chronic low back pain, spinal stenosis, or radicular pain syndromes.

The American Society of Interventional Pain Physicians (ASIPP)
In their practice guidelines on the management of chronic spinal pain, the ASIPP states that that the evidence for lumbar epidural adhesiolysis in managing chronic low back and leg pain secondary to post lumbar surgery syndrome is fair to good and spinal stenosis is fair. The guidelines also recommend percutaneous adhesiolysis after failure of conservative management and fluoroscopically directed epidural injections (2013).

Functional Anesthetic Discography (FAD)
Luchs et al. (2007) presented their preliminary experience with FAD in the evaluation of patients with suspected discogenic low back pain at the 2007 American Roentgen Ray Society Annual Meeting (Abstract #152, May 8th). For the study, investigators performed FAD in 19 patients (13 men, 6 women; mean age 47.2 years) who underwent lumbar discography for suspected discogenic low back pain. A total of 29 discs were injected with anesthetic and then studied using discography and CT examination. In addition, patients were asked to perform maneuvers that would typically elicit their pain symptoms. Nineteen of the 29 (65.5%) injected discs showed a favorable response (pain relief greater than 3 visual analog pain scale units) compared with ten (34.5%) injected discs that did not show a favorable response. In those patients with a favorable FAD response, 19 discs showed a provocative response during discography and 18 discs showed the presence of disc pathology on CT examination. In patients with an unfavorable FAD response, 8 discs showed a provocative discographic response, and 6 discs showed the presence of disc pathology on CT examination. The authors cautioned that even though FAD seemed to work in some cases, it often actually raised more questions as to diagnosis.

A case series by Alamin et al. (2008) presented the findings of 3 patients in whom FAD was used for the evaluation of presumptive discogenic low back pain. Of the 3 patients, only 1 patient had the results from a provocative discography confirmed by FAD. The authors concluded that further studies are needed in order to make more definitive recommendations with regards to the validity and utility of this new technique.

Alamin et al (2011) compared the results of standard pressure-controlled provocative discography (PD) to those of the functional anesthetic discogram (FAD) in a prospective series of 52 patients presenting with chronic low back pain. Standard pressure-controlled PD was performed, followed by (in positive cases or in patients with clinical features and imaging studies felt to be highly suggestive of symptomatic disc degeneration) an FAD. Discordant results of the two tests were noted in 46% of the patients in the series. Of them, 26% of patients with positive PD had negative findings on the FAD test; 16% had positive findings at a single level only, whereas the provocative discogram had been positive at two or more levels; 4% had new positive findings on the FAD test. The authors concluded that further studies are needed to demonstrate the clinical utility of the test.

Although researchers are presently investigating the use of functional anesthetic discography for diagnosing discogenic pain, there is insufficient evidence in the published, peer-reviewed scientific literature to support safety and efficacy at this time.

Professional Societies
American College of Occupational and Environmental Medicine (ACOEM)
The ACOEM Guideline Summary for Low Back Pain (LBP) states that discography, whether performed as a solitary test or when paired with imaging (e.g., MRI), for acute, subacute, chronic LBP or radicular pain syndromes is “moderately not recommended” (2011).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)
Endoscopes, catheters, and needles that can be used for epidural lysis of adhesions are regulated by the FDA as Class II devices and a number of these devices have been approved via the FDA 510(k) process. The Racz Catheter received FDA approval on October 8, 1996 (K954584). The Myelotec Myeloscope received 510(k) approval on September 4, 1996 (K960194). Additional information, product codes HRX, BSO, and BSP, is available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed September 12, 2016)
The FAD System (originally developed by InnoSpine and later acquired by Kyphon Inc.) received 510(k) approval through the U.S. Food and Drug Administration (FDA) in April 2005 (FDA, K043500). According to the FDA, the intended use of the system is to deliver either a single dose or continuous administration of radiopaque contrast, local anesthetics, and/or saline solution to the intradiscal space. Additional information is available at: http://www.accessdata.fda.gov/cdrh_docs/pdf4/K043500.pdf. (Accessed September 12, 2016)

The Discyphor™ catheter system (Kyphon, Inc., Sunnyvale, CA, USA, part of Medtronic Spine LLC) is intended to help diagnose the cause of chronic low back pain. The Discyphor system uses a proprietary balloon anchor that allows the practitioner to anesthetize a patient’s symptomatic disc(s) before the patient performs activities that would typically elicit pain. A prior version of the Discyphor Catheter System called the Functional Anesthetic Discography System (InnoSpine, Inc., Los Altos Hills, CA, USA), was first cleared for marketing by the U.S. Food and Drug Administration (FDA) in 2005. InnoSpine was acquired by Kyphon in 2006. Later in 2006, Kyphon received clearance for marketing of the Functional Anesthetic Discography Catheter. In 2007, FDA cleared for marketing the Discyphlor Catheter System.

REFERENCES

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by UnitedHealthcare Medical Technology Assessment Committee. [2017T02060]


National Institute for Health and Care Excellence (NICE) [website]. Therapeutic endoscopic division of epidural adhesions. February 2010.


POLICY HISTORY/REVISION INFORMATION

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>01/01/2017</td>
<td>• Reformatted and reorganized policy; transferred content to new template</td>
</tr>
<tr>
<td></td>
<td>• Updated benefit considerations; added instruction to check the member specific</td>
</tr>
<tr>
<td></td>
<td>benefit plan document and any federal or state mandates, if applicable, before</td>
</tr>
<tr>
<td></td>
<td>using this policy</td>
</tr>
<tr>
<td></td>
<td>• Updated supporting information to reflect the most current description of</td>
</tr>
<tr>
<td></td>
<td>services, clinical evidence, and references; no change to coverage rationale or</td>
</tr>
<tr>
<td></td>
<td>list of applicable codes</td>
</tr>
<tr>
<td></td>
<td>• Archived previous policy version PAIN 004.17 T2</td>
</tr>
</tbody>
</table>