

# EPIDUROSCOPY, EPIDURAL LYSIS OF ADHESIONS AND FUNCTIONAL ANESTHETIC DISCOGRAPHY

**Guideline Number:** MMG042.H

**Effective Date:** December 1, 2018

See [Instructions for Use](#) ⓘ

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## COVERAGE RATIONALE

**The following are unproven and not medically necessary for the diagnosis or treatment of any type of neck, back, or spinal disorder due to insufficient evidence of its effectiveness:**

- Epiduroscopy (including spinal myeloscropy)
- Percutaneous and endoscopic epidural lysis of adhesions
- Functional anesthetic discography (FAD)

## 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 guideline 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 and Guidelines may apply.

CPT Code	Description
62263	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
62264	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
64999	Unlisted procedure, nervous system

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**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 and introducer system.

Epidural lysis of adhesions (LOA) (adhesiolysis, percutaneous epidural neuroplasty epidurolysis) is a minimally invasive procedure for individuals who have epidural adhesions that are thought to cause chronic low back pain (LBP). The procedure is often performed using local anesthesia and a mild sedative, so the individual 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, Updated 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 individual 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 individual 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.

Hazer et al. (2018) conducted a retrospective study of 88 patients with chronic LBP and radicular pain secondary to lumbar disc herniation to evaluate the efficacy of epiduroscopy in this patient population, whether or not they have undergone prior surgery. Of the study group, 66 participants had a history of prior back surgery and 22 did not. Diagnostic epiduroscopy was performed on all patients, including washing of the epidural space with saline and removal of inflammatory agents from the space via adhesiolysis. Each procedure ended with a steroid injection into the epidural space. All patients received a clinical examination on the day of the surgery, and then after 1, 6, and 12 months. All the patients evaluated their pain on a Visual Analog Scale (VAS) and validated their disability using the ODI questionnaire on all visits. All patients improved significantly in pain (VAS) and disability (ODI) at 1 month and 1 year. No differences were found between men and women at the different follow-up times. A slight worsening in VAS and ODI was noticed over time except for the non-operated group. The authors concluded that epiduroscopy with adhesiolysis and steroid injection helps to relieve pain and reduce disability in patients with back and leg pain due to lumbar disc herniation, regardless of gender. Patients who had not had previous surgery seemed to benefit more from the treatment. The improvement in pain relief and reduced disability seemed to last for at least 1 year.

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.

Igarashi et al. (2004) conducted a study of 58 patients with degenerative lumbar spinal stenosis who were placed into 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 LBP 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 (RCTs), are necessary to evaluate the safety and efficacy of epiduroscopy.

### **Epidural Lysis of Adhesions**

Rapcan et al. (2018) conducted a randomized, multicenter, double-blind parallel pilot study comparing the efficacy of drugs (the enzyme hyaluronidase and corticosteroid DEPO-Medrol) administered during epiduroscopy with standard treatment, focusing on releasing foraminal adhesions. Study participants (n=48) with a diagnosis of failed back surgery syndrome were randomized into 2 groups prior to epiduroscopy. Group A received mechanical lysis of fibrotic tissue in the epidural space (considered standard treatment), while Group B received medications. Subjects were

followed for 6 and 12 months via scheduled double-blinded examinations by pain physicians. Leg and back pain intensity was assessed by an 11-point numerical rating scale, and patients' functional disability was assessed by the ODI. Participants showed a significant decrease in ODI score as well as significantly lower scores for leg and back pain in both groups at 6 months. However, the 1-year follow-up showed a return to the baseline ODI values of most monitored pain scores in both groups. Improvement was only noted on the numerical rating scale for back pain at 1 year. The authors concluded that while epiduroscopy with either standard treatment or drug therapy resulted in significant improvement of leg and back pain after 6 months, drug treatment was more durable for this study group.

Lee et al. (2014) conducted a systematic review on the subject of epidural lysis of adhesions (LOA). Evidence based literature considered in the review included clinical trials, various studies (observational, retrospective, prospective, and animal), review articles, case series and reports, and guidelines published between 1970 and 2013. The efficacy of epidural LOA in the cervical region has been addressed in several studies, none of which were randomized trials. In one cited study (Park et al., 2013), baseline data was not reported, making it difficult to accurately interpret data during the follow-up period. Interventions performed on the cervical spine were noted to be associated with higher complication rates and possible additional risks when compared to like procedures at other spinal levels. Regarding the lumbar region, epidural LOA was evaluated in diagnoses including but not limited to pain in the low back and lower extremities, post lumbar surgery syndrome, and refractory radiculopathy. Many studies (including Manchikanti, 2004 and Veihelmann, both described below) indicate that epidural LOA has good long-term benefit and is superior to conventional epidural steroid injection and conservative therapy; however, discrepancy exists among systematic reviews regarding the strength of the evidence. Limitations to the studies include conclusions and recommendations being impacted by the paucity of high-quality randomized studies and the lack of trials performed by a broader group of clinician investigators, as well as the lack of randomized studies comparing percutaneous and endoscopic LOA and lack of factors associated with outcomes. The authors concluded that the evidence surrounding LOA at any vertebral level is still controversial. Larger, more methodologically sound studies that compare adhesiolysis to placebo and to other treatments are needed to better determine effectiveness.

In 2013, Helm et al. published a systematic review evaluating and updating the effectiveness of spinal endoscopic adhesiolysis in treating post lumbar surgery syndrome. Twenty one studies published between 1966 and September 2012 were identified. Of these, one RCT and 5 observational studies met the inclusion criteria. Two of the observational studies were excluded because of other methodological issues. Pain relief and functional improvement were the primary outcome measures. Other outcome measures were improvement of psychological status, opioid intake, and return to work. Short-term effectiveness was defined as improvement of 12 months or less, and long-term efficacy was 12 months or more. Using USPSTF criteria, the authors concluded that the evidence is fair that endoscopic adhesiolysis is effective in treating chronic low back and/or lower extremity pain caused by post lumbar surgery syndrome, and should be considered to be low risk for serious adverse complications. Limitations of this study include the paucity of literature. There are also noted conflicts of interest with several of the researchers which may limit the conclusions that can be drawn from the study.

A similar study was conducted in 2016 by Helm & colleagues to evaluate the efficacy of percutaneous adhesiolysis and spinal endoscopic adhesiolysis in the treatment of chronic refractory low back and lower extremity pain. In this systematic review, 45 studies were identified. Of these, 7 RCTs and 3 observational studies on percutaneous adhesiolysis met the inclusion criteria. For spinal endoscopy, there was 1 RCT and 3 observational studies. Primary outcome measures were pain relief of at least 50% and functional improvement of at least 40%. Short-term efficacy was defined as improvement of 6 months or less, and long-term efficacy was more than 6 months. The researchers concluded that percutaneous epidural adhesiolysis to treat refractory low back and lower extremity pain is safe and effective, supported by multiple RCTs. However, endoscopic adhesiolysis is a technique which has limited evidence supporting its use. Additional studies regarding this technology are in progress. Conflicts of interest are again cited with several of the researchers which may limit the study's conclusions.

Hong Park and Ho Lee (2017) conducted a prospective study of 78 patients with degenerative lumbar spinal stenosis to assess the relationship between improvement shown on epidurogram and subjective patient response after undergoing percutaneous adhesiolysis. Each subject underwent MRI of the lumbar spine, with all therapeutic procedures conducted in the operating room. Two weeks later, a second epidurography was performed to assess any change in epidural filling defects. Outcome measures were obtained using the VAS score at 2, 4, and 12 weeks post-treatment. All of the participants displayed epidural filling defects at baseline. After percutaneous adhesiolysis, epidurographic filling defects were absent in 73% of patients. In the presence or absence of filling defects, mean VAS scores were 5.2 and 4.5 at 2 weeks, respectively. There was no significant correlation between postprocedural VAS score and status of filling defects (yes or no) at 3 months. The authors' conclusion was that epidurographic findings following percutaneous epidural adhesiolysis failed to correlate with level of pain reduction achieved in patients with degenerative lumbar spinal stenosis.

Donato et al. (2011) conducted a prospective study evaluating the efficacy of endoscopic epidural LOA on 234 individuals with chronic LBP. Participants received epidurolysis via flexible fiberoptic endoscope through which saline

combined with targeted doses of hyaluronidase, ozone, or ciprofloxacin were instilled. Reduction in VAS scores and ODI were considered as positive outcomes. Post-procedural status was monitored at 1 week, then at 3, 6, 12, 24, 36, and 48 months, with positive outcomes reported throughout the follow up period. The authors concluded that in this study, mechanical adhesiolysis via endoscopic approach was effective in providing durable pain relief in chronic LBP. Although positive outcomes were reported, the study was limited by the lack of a control group.

A randomized, double-blind trial was conducted by Gerdesmeyer et al. (2013) to analyze the clinical efficacy of percutaneous epidural LOA in chronic radicular pain. Out of 381 patients with 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 ODI scores 3 months post-procedure. Secondary outcome measures were difference in percent change of ODI scores and VAS scores. The ODI and VAS scores as well as the success rates for ODI vs VAS were significantly better at 3, 6, and 12 months in the lysis group vs the control group. The ODI in the lysis group improved from 55.3 ( $\pm$  11.6) to 26.4 ( $\pm$  10.8) after 3 months. The placebo group improved from 55.4 ( $\pm$  11.5) to 41.8 ( $\pm$  14.6). VAS improved from 6.7 ( $\pm$  1.1) to 2.9 ( $\pm$  1.9) in the active group and from 6.7 ( $\pm$  1.1) to 4.8 ( $\pm$  2.2) after placebo. Twelve month follow-up shows further improvement, with the differences remaining 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 RCT 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), ODI, employment status, and opioid intake. Follow-up occurred at 3, 6, and 12 months post treatment. In the adhesiolysis group, the average number of procedures performed was 3.5 with pain relief reported for 42 out of 52 weeks. Pain relief and functional status improvement were >50% and 73% of patients, respectively. The epidural steroid group averaged 2.2 injections and achieved pain relief for 13 out of 52 weeks. Only 12% of patients reported pain relief and improved 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. The significant number of patients lost to follow-up in the epidural steroid group limits the ability to accurately compare the 2 procedures.

Another RCT 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 associated with lumbar central spinal stenosis. There were 25 patients in each group. Outcomes were measured using the NRS, 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 normal saline while Group II had targeted catheter placement to the level of the defect and injection of 10% sodium chloride solution. The study showed pain relief in 76% of the adhesiolysis group at 1 year 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. (2013b) evaluated the effectiveness of percutaneous epidural adhesiolysis in 70 patients with chronic low back and lower extremity pain secondary to 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 non-particulate 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 LBP and sciatica to investigate whether minimally invasive techniques for adhesiolysis are superior to conservative treatment with PT. Patients were randomly assigned into either a group with PT (n=52) or a group undergoing epidural neuroplasty (n=47). Patients were assessed before and at 3, 6, and 12 months post treatment by a blinded investigator. After 3 months, the (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 ODI 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 improvement of pain and functional disability in patients with chronic LBP 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 PT 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 PT chose to undergo epidural adhesiolysis so 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 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. VAS pain scores, ODI, 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-months. 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 months (+/- 1.49 months) in Group II and 3.8 months (+/- 3.37 months) in Group III. The authors concluded that percutaneous adhesiolysis, with or without hypertonic saline neurolysis, is an effective treatment for chronic LBP.

A systematic review by Epter et al. (2009) which included the Veihelmann and Manchikanti (2004) studies described above 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. All of the 3 randomized trials showed positive results for short and long-term relief. All 4 of the 4 observational studies reflected positive short-term improvement, but only 3 of 4 reported positive 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.

There are open clinical trials studying epiduroscopy and epidural lysis of adhesions for LBP. There are no trials identified studying these procedures for cervical spine conditions. For more information, please go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

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.

### **National Institute for Health and Care Excellence (NICE)**

A 2010 statement 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. Further research on this procedure should clearly describe case selection. Outcomes should include pain relief, duration of effectiveness and whether other treatments are subsequently required.

### **Professional Societies**

#### **American Society of Interventional Pain Physicians (ASIPP)**

The ASIPP recommends percutaneous adhesiolysis in patients with post lumbar surgery syndrome and lumbar central spinal stenosis after failure of conservative management of physical therapy, chiropractic, drug therapy, structured exercise program, and fluoroscopically directed epidural injections. Due to limited evidence and rare use of spinal epidural endoscopic adhesiolysis, this technique was not discussed. (Manchikanti et al, 2013a)

#### **American Academy of Neurological Surgeons (AANS)**

The AANS does not include percutaneous or endoscopic LOA as a treatment for disorders of the cervical or lumbar spine (2018).

## **American Academy of Orthopaedic Surgeons (AAOS)**

The AAOS does not include percutaneous or endoscopic LOA as a treatment for disorders of the neck and back (2013).

### **Functional Anesthetic Discography (FAD)**

Luchs et al. (2007) presented their preliminary experience with FAD in the evaluation of patients with suspected discogenic LBP at the 2007 American Roentgen Ray Society Annual Meeting (Abstract #152, May 8th). For the study, investigators performed FAD in 19 patients who underwent lumbar discography for suspected discogenic LBP. 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 VAS 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 LBP. Of the 3 patients, only 1 patient had the results from a provocative discography (PD) 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 PD to those of the FAD in a prospective series of 52 patients presenting with chronic LBP. 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) FAD. Discordant results of the 2 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 PD had been positive at 2 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.

A 2017 Hayes report on the clinical utility of lumbar discography for assessing LBP excluded studies using anesthetic discography or FAD. Their report cites very little evidence that discography improves health outcomes in patients with chronic LBP, and that the majority of the studies reviewed either did not report on complications or did not use systematic methodologies to collect and report safety outcomes.

There are no clinical trials studying FAD that are either recruiting or in progress.

Given the lack of robust published peer reviewed literature, there is insufficient evidence to support the safety and efficacy of FAD at this time.

### ***Professional Societies***

#### **American Society of Interventional Pain Physicians (ASIPP)**

The ASIPP states that there is limited evidence supporting the diagnostic accuracy of FAD. They are silent on any recommendation for its use (Manchikanti et al., 2013).

#### **American College of Radiology (ACR)**

In its 2015 appropriateness criteria for patients with LBP, the ACR finds PD to be controversial when attempting to identify a discogenic source of lumbar pain, secondary to the subjective nature of the test. X-ray discography, also controversial, may be useful for patients with chronic LBP lasting longer than 3 months. The criteria are silent on FAD.

### **U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

Products such as endoscopes, catheters, and needles that can be used for epidural LOA are numerous. See the following website for more information and search by product name in the device name section: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm> (Accessed July 25, 2018).

Products intended to help diagnose the cause of chronic LBP are numerous. See the following website for more information and search by product name in the device name section: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm> (Accessed July 25, 2018).

### **REFERENCES**

Alamin T, Malek F, Carragee E, et al; The functional anaesthetic discogram: Description of a novel diagnostic technique and report of 3 cases; SAS Journal; 2008; 2: 107-113.

Alamin TF, Kim MJ, Agarwal V; Provocative lumbar discography versus functional anesthetic discography: a comparison of the results of two different diagnostic techniques in 52 patients with chronic low back pain; *Spine J* 2011 Aug; 11 (8) 756-65.

American Academy of Neurological Surgeons. Patient Information/Neurosurgical Conditions and Treatments. 2018. <http://www.aans.org/en/Patients/Neurosurgical-Conditions-and-Treatments>. Last update 2018.

American Academy of Orthopaedic Surgeons. Patient Education/Neck Pain. <https://orthoinfo.aaos.org/en/diseases--conditions/neck-pain/>. Last update 2013.

American Academy of Orthopaedic Surgeons. Patient Education/Low Back Pain. <https://orthoinfo.aaos.org/en/diseases--conditions/low-back-pain/>. Last update 2013.

American College of Radiology. Appropriateness Criteria/Low Back Pain. Last review date 2015.

Bosscher HA, Heavner JE. Lumbosacral epiduroscopy findings predict treatment outcome. *Pain Pract.* 2014 Jul;14(6):506-14.

Donato AD, Fontana C, Pinto R et al; The effectiveness of endoscopic epidurolysis in treatment of degenerative chronic low back pain: a prospective analysis and follow-up at 48 months; *Acta Neurochir Suppl* 2011; 108: 67-73.

Epter R, Helm S, Hayek S, et al; Systematic Review of Percutaneous Adhesiolysis and Management of Chronic Low Back Pain in Post Lumbar Surgery Syndrome; *Pain Physician* 2009; 12: 361-378.

Gerdesmeyer L, Wagenpfeil S, Birkenmaier C, et al; Percutaneous epidural lysis of adhesions in chronic lumbar radicular pain: a randomized, double-blind, placebo-controlled trial; *Pain Physician*; 2013 May-Jun; 16 (3): 185-96.

Hayes Inc. Medical Technology Directory. The Clinical Utility of Lumbar Discography for Assessing Low Back Pain: Impact on Patient Management and Health Outcomes. Lansdale, PA: Hayes, Inc. September 7, 2017.

Hayes Inc; Health Technology Brief; Percutaneous Epidural Adhesiolysis for Chronic Back Pain; Lansdale, PA: Hayes, Inc; December 27, 2013; Updated December 15, 2015. Archived January 27, 2017.

Hazer DB, Acarbaş A, Rosberg HE. The outcome of epiduroscopy treatment in patients with chronic low back pain and radicular pain, operated or non-operated for lumbar disc herniation: a retrospective study in 88 patients. *Korean J Pain.* 2018 Apr;31(2):109-115.

Helm S 2nd, Racz GB, Gerdesmeyer L, et al. Percutaneous and Endoscopic Adhesiolysis in Managing Low Back and Lower Extremity Pain: A Systematic Review and Meta-analysis. *Pain Physician.* 2016 Feb;19(2):E245-82.

Helm S, Hayek SM, Colson J, et al. Spinal endoscopic adhesiolysis in post lumbar surgery syndrome: an update of assessment of the evidence. *Pain Physician.* 2013 Apr;16(2 Suppl):SE125-50. Review.

Hong Park C, Ho Lee S. Epidurographic Findings Following Percutaneous Epidural Adhesiolysis Failed to Correlate with Level of Pain Reduction in Patients with Lumbar Spinal Stenosis. *Pain Med.* 2017 May 1;18(5):842-845.

Igarashi T, Hirabayashi Y, Seo N, et al; Lysis of adhesions and epidural injection of steroid/local anaesthetic during epiduroscopy potentially alleviate low back and leg pain in elderly patients with lumbar spinal stenosis; *Br J Anaesth*; 2004 Aug; 93 (2): 181-7.

Lee, F, Jamison D, Hurley R, et al.; Epidural Lysis of Adhesions; *Korean J Pain*; 2014 Jan; 27 (1): 3-15.

Luchs JS, Sofka CM, Adler RS; Sonographic contrast effect of combined steroid and anesthetic injections: in vitro analysis; *J Ultrasound Med*; 2007 Feb; 26 (2): 227-31.

Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician* 2013a Apr;16(2 Suppl):S49-283.

Manchikanti L, Cash KA, McManus C, et al; The Preliminary Results of a Comparative Effectiveness Evaluation of Adhesiolysis and Caudal Epidural Injections in Managing Chronic Low Back Pain Secondary to Spinal Stenosis: A Randomized, Equivalence Controlled Trial; *Pain Physician*; 2009b; 12: E341-E354.

Manchikanti L, Cash KA, McManus CD, et al. Pampati V; Assessment of Effectiveness of Percutaneous Adhesiolysis in Managing Chronic Low Back Pain Secondary to Lumbar Central Spinal Canal Stenosis; *Int J Med Sci* 2013b; 10 (1): 50-59.

Manchikanti L, Rivera JJ, Pampati V, et al; One Day Lumbar Epidural Adhesiolysis and Hypertonic Saline Neurolysis in Treatment of Chronic Low Back Pain: A Randomized, Double-Blind Trial; *Pain Physician*; 2004; 7: 177-186.

Manchikanti L, Rivera JJ, Pampati V, et al; Spinal endoscopic adhesiolysis in the management of chronic low back pain: A preliminary report of a randomized, double-blind trial; *Pain Physician*; 2003; 6 (3): 259-267.

Manchikanti L, Singh V, Cash KA, et al; A comparative effectiveness evaluation of percutaneous adhesiolysis and epidural steroid injections in managing lumbar post surgery syndrome: a randomized, equivalence controlled trial; *Pain Physician*; 2009a; 12 (6): E355-E368.

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

Park CH, Lee SH, Lee SC. Preliminary results of the clinical effectiveness of percutaneous adhesiolysis using a Racz catheter in the management of chronic pain due to cervical central stenosis. *Pain Physician*. 2013 Jul-Aug; 16(4):353-8.

Rapcan R, Kocan L, Mlaka J, et al. A Randomized, Multicenter, Double-Blind, Parallel Pilot Study Assessing the Effect of Mechanical Adhesiolysis vs Adhesiolysis with Corticosteroid and Hyaluronidase Administration into the Epidural Space During Epiduroscopy. *Pain Med*. 2018 Mar 23.

Veihelmann A, Devens C, Trouillier H, et al; Epidural neuroplasty versus physiotherapy to relieve pain in patients with sciatica: a prospective randomized blinded clinical trial; *J Orthop Sci*; 2006 Jul; 11 (4): 365-9.

#### **GUIDELINE HISTORY/REVISION INFORMATION**

Date	Action/Description
12/01/2018	<ul style="list-style-type: none"><li>• Reorganized policy template:<ul style="list-style-type: none"><li>◦ Simplified and relocated <i>Instructions for Use</i></li><li>◦ Removed <i>Benefit Considerations</i> section</li></ul></li><li>• Simplified coverage rationale (no change to guidelines)</li><li>• Archived previous policy version MMG042.G</li></ul>

#### **INSTRUCTIONS FOR USE**

This Medical Management Guideline provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard benefit plan. In the event of a conflict, the member specific benefit plan document governs. Before using this guideline, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Management Guideline is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. UnitedHealthcare West Medical Management 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.

Member benefit coverage and limitations may vary based on the member’s benefit plan Health Plan coverage provided by or through UnitedHealthcare of California, UnitedHealthcare Benefits Plan of California, UnitedHealthcare of Oklahoma, Inc., UnitedHealthcare of Oregon, Inc., UnitedHealthcare Benefits of Texas, Inc., or UnitedHealthcare of Washington, Inc.