Epiduroscopy, Epidural Lysis of Adhesions and Discography

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Instructions for Use

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- Epiduroscopy, Epidural Lysis of Adhesions and Discography

Application

UnitedHealthcare Commercial

This Medical Policy applies to all UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans in all states except for Colorado.

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 efficacy:

- Discography
  - Functional anesthetic discography
  - Provocative discography
  - Chemonucleolysis
- Epiduroscopy (including spinal myeloscopy)
- Percutaneous and endoscopic epidural lysis of adhesions

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 and Guidelines may apply.

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

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
62290	Injection procedure for discography, each level; lumbar
62291	Injection procedure for discography, each level; cervical or thoracic
62292	Injection procedure for chemonucleolysis, including discography, intervertebral disc, single or multiple levels, lumbar
64999	Unlisted procedure, nervous system
72285	Discography, cervical or thoracic, radiological supervision and interpretation
72295	Discography, lumbar, radiological supervision and interpretation

Description of Services

Epiduroscopy is a procedure which requires removal of adhesions and fibrosis using a laser, the tip of the flexible catheter and saline flushing. In the final stage, steroids are administered to help cleanse the inflammatory agents in the epidural space. With this technique, the epidural space can easily be monitored, anatomic structures identified, and pathologies detected (Hazer, 2018).

Chemonucleolysis is a minimally invasive procedure that consists of injecting of a proteolytic enzyme into the intervertebral disc for the purpose of dissolving the herniated nucleus pulposus; this procedure has been proposed as a solution to bridge the gap between conservative therapy and surgical intervention. Chymopapain was the first protein enzyme identified and used for chemonucleolysis; it was discontinued due to safety concerns. New enzymes continue to be developed and studied for their safety and effectiveness.

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 adhesiolysis (PA) (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.

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.

Provocative discography (PD) is an invasive diagnostic spine procedure that involves the administration of contrast into the nucleus pulposus of an intervertebral disc to determine if the disc is the origin of a patient's chronic spine pain. The test is based on the premise that discs can be a source of spine pain, and symptomatic, internally disrupted disc causes pain when it is mechanically loaded; therefore, it should be similarly painful when pressurized with injected contrast (Gruver and Guthmiller, 2019).

Discography

The available evidence is limited and low in quality for the clinical utility of discography for diagnosis and/or treatment of spinal disorders. Additional well-designed, long-term, randomized controlled clinical trials are needed for evaluation of efficacy and long-term effects.

A 2023 Hayes evidence analysis research brief on the clinical utility of lumbar discography for assessing low back pain (LBP) identified two new abstracts since 2017 that evaluated treatment guided by lumbar discography when compared with no surgery or no discography control group. The first was a 2023 prospective comparative study from Sweden which evaluated discography and MRI for low back pain in 17 individuals. The authors found no differences in longitudinal change of MRI parameters between the patients with low back pain treated with or without fusion surgery. The other study was a 2022 retrospective cohort study on in the U.S. on 104 patients which evaluated provocative discography for degenerative disc disease (DDD). The authors concluded patients that underwent a provocative discogram and fusion had a higher rate of subsequent degeneration than those patients with similar low back pain with no discogram.

In a 2022 retrospective cohort analysis, Pinto et al. (included in the 2023 Hayes research brief above) reported on the efficacy and safety of provocative discography for symptomatic DDD. The study compared patients who received a provocative discogram (53 subjects, 193 disks) to a control group (51 subjects, 255 disks) that included patients with a history of LBP that did not have a discogram, and at least 2 sets of lumbar MRI with a minimum of 5 years in between. Descriptive summaries were generated by group for each level and for all levels combined. Normal disks (no inner annular fissure, full-thickness tear, dye leak (discogram group), Schmorl node, venous filling, or narrowing) were identified on index MRIs for both groups. The same disks were then graded normal or degenerated on follow-up MRIs of 8 years for the index and 11 years for the control group. The results showed in the discogram group there were 68 normal disks, and on follow up MRI, 25 remained normal. In the control group there were 90 normal disks and 30 showed degeneration at follow up. There were no infections, deaths or long-term neurological injuries. The authors concluded that provocative discograms have good efficacy in the identification of DDD but concerns for accelerated disk degeneration adjacent to previous fusion may still exist. However, following stratification of discography subjects, they found it did not increase this risk. Limitations include a small number of participants and further research is needed to validate these findings.

Cuellar et al. investigated the clinical effects of lumbar PD on patients subjected to this evaluation method in a prospective, 10-year matched cohort study. Subjects (n = 75) without current LBP problems were recruited to participate in a study of PD at the L3-S1 discs. A closely matched control cohort (n = 75) was simultaneously recruited to undergo a similar evaluation except for discography injections. Primary outcome variables were diagnostic imaging events and lumbar disc surgery events. Secondary outcome measures were serious LBP events, disability events, and medical visits. All subjects were followed by serial protocol evaluations at one, two, five, and ten years after enrollment. Of the 150 subjects, 71 discography subjects and 72 control subjects completed the baseline evaluation. At ten years, study and control subjects completing all interval surveillance evaluations were 57 and 53, respectively. There were 16 lumbar surgeries in the study group, compared with four in the control group. Medical visits, computed tomography (CT)/ magnetic resonance imaging (MRI) examinations, work loss, and prolonged back pain episodes were all more frequent in the discography group compared with control subjects. The author's results demonstrated a significantly higher rate of lumbar spine surgery in patients who are exposed to discography. However, it was noted that most patients exposed to discography did not eventually require surgery. While the researchers concluded that disc puncture and pressurized injection performed during PD can increase the risk of clinical disc problems, they suggested that longer term follow-up of patients exposed to lumbar PD could provide more answers. Limitations of the study included loss to follow up over the ten-year period and the inability to assess the outcomes in all patients (2016).

In a 2015 review on the evaluation and treatment of LBP, Hooten and Cohen stated that while touted as the only means to establish a relationship between disc pathology and symptoms, PD is characterized by a high false-positive rate in some patients (Provenzano, 2012). Additionally, they state that the evidence that discography may improve surgical outcomes is limited to a subgroup analysis of a single randomized study (Margetic et al., 2013) comparing outcomes in individuals who did and did not undergo pre-fusion discography.

Alamin et al. 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 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 PD 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 (2011).

Chemonucleolysis

Chemonucleolysis is a minimally invasive treatment option for patients experiencing lumbar disc herniation, however the evidence is limited. Additional long-term, randomized controlled clinical trials are needed for evaluation of safety, efficacy, long-term effects, and optimal chemonucleolysis agent.

A clinical evidence assessment by ECRI (2022) focused on Discogel's safety and efficacy for treating lumbar degenerative disc disease. Limited evidence identified no RCTs that compared Discogel therapy with an alternative treatment. And while low quality evidence suggests Discogel therapy is safe, reduces pain, and improves symptoms for patients with lumbar degenerative disc disease, there was no evidence to determine whether the Discogel therapy worked as well or better than other treatments.

Kelekis et al. (2022) compared treatment and clinical outcomes of intradiscal oxygen-ozone treatment to that of microdiscectomy in patients with lumbar disc herniations radiculopathy. Forty-nine participants between 18 and 65 years, with leg pain intensity NRS ≥ 5.0, and symptoms lasting at least 6 weeks, or more were randomized into a 1:1 ratio to either receive oxygen-ozone intradiscal injection or microdiscectomy. The intradiscal oxygen-ozone injections were performed on patients under conscious sedation while the microdiscectomy was performed under general anesthesia. Participants were evaluated at baseline, 1 week, 1-, 3- and 6 months. The Numerical Rating Scale (NRS) was used to assess leg pain on a scale of 0-10 at each visit; other measured clinical outcomes included separate NRS scores for back pain, Roland Morris Disability Index (RMDI), and the EQ-5D quality of life questionnaire. The primary endpoint was improvement in leg pain over six months based on the NRS. The authors found the mean scores for leg pain and back pain had significantly improved for both groups; and thus, concluded that the intradiscal oxygen-ozone treatment was no worse than the microdiscectomy procedure. Limitations included significantly small sample size which limited the estimation of safety for both treatments; in addition, the study was not powered to detect adverse events.

Banno et al. (2021) performed a retrospective study aimed to assess radiographs after chemonucleolysis with condoliase and examine one-year clinical outcomes. Sixty patients (37 men, 23 women) with lumbar disc herniation (LDH) who received condoliase injection with a follow-up period of greater than one year were included in the study. Using MRI, changes in disc height and degeneration were evaluated. Visual analogue scale (VAS) scores for leg and back pain and the Oswestry Disability Index (ODI) were obtained. Data was assessed at baseline, 1-month, 3-month, and 1-year follow-up. Surgical treatment was required in eight patients (12.5%) after condoliase therapy. ODI and VAS scores for leg pain and back pain significantly improved at one year, as in those who received condoliase therapy only. On MRI, progression of Pfirrmann grade was observed in 23 patients (44.2%) at three months; however, eight patients recovered to baseline at one year. The mean disc height decreased at three months but recovered at one year. Disc height recovery was observed in 30.8% of the patients. Patients with disc height recovery were significantly younger than those without. Patients with longer symptom duration (≥ 1 year) showed significantly lower rates of effectiveness compared with those with shorter symptom durations (< 1 year). The authors concluded chemonucleolysis with condoliase is a safe, minimally invasive, highly effective treatment that could be an alternative treatment for LDH but acknowledged 12.5% of patients required surgical treatment within one year after condoliase therapy. Additionally, disc degeneration induced by chemonucleolysis could be recovered, particularly in younger patients and prolonged symptom duration had adverse effects on outcome. The authors noted the study limitations as a relatively small sample size, the mean follow-up period of 22.0 ±6.0 months was short, and clinical outcomes between patients who underwent intradiscal condoliase therapy and conservative controls were not compared. The authors recommended further clinical surveys involving a larger number of patients with longer follow-up periods were needed to determine the prognostic factors for condoliase therapy and changes in disc degeneration. In 2022, the same author, Banno et al. reported the two-year clinical outcomes of this study. The results showed a similar outcomes with no symptom recurrence or radiographically evidence of re-protrusion of the disk at the same level. Progression of disc degeneration was observed in 57.1% of patients at three months; however, 30% recovered to baseline at two years. The mean disc height decreased at three months but recovered slightly at one year and remained stable until two years. The authors concluded that chemonucleolysis with condoliase is an effective alternative treatment for LDH up to 2 years following treatment. These findings are limited by a small number of participants and

short follow up period, and further research involving larger numbers of participants and longer follow up are needed to validate these findings. Furthermore, the clinical outcomes were not compared to outcomes of conservative treatment or surgery. Ishibashi et al. (2020) reviewed condoliase for 34 patients with low back and leg pain. Twenty-four men and ten women conservatively treated with medications and block therapy for at least one month and did not wish to undergo surgery were offered the condoliase injection. The numerical rating scale (NRS) was conducted before the procedure and three months after. The straight leg raising test was also implemented prior to the procedure. MRI was done one month before the procedure and again one month and three months afterwards. The patients were divided into two groups: good group (G) which contained a NRS score improvement of ≥ 50% and the poor group (P) which contained those with a score of < 50% improvement. The authors analysis demonstrated that condoliase was more effective for the leg pain versus the LBP. It was concluded that the condoliase injection was safe and effective for those that had experienced no relief during conservative treatment. Limitations included small sample size, imbalance of male to female ratio, and no long-term follow-up.

Okada et al. (2020) reviewed eighty-two patients with lumbar disc herniation for the safety and efficacy of chemonucleolysis. The condoliase was injected into the intervertebral space and performed or supervised by a qualified orthopedic spine surgeon. The patients were monitored closely for three hours following the injection and discharged the next day. All participants were assessed with the visual analogue scale (VAS) and results were considered positive if the leg pain improved 50% or more after six months. The authors found 85% of patients had effective results with chemonucleolysis; surgical treatment was later required in four patients due to the continued severe leg pain following the chemonucleolysis procedure. The study revealed favorable results for patients with lumbar disc herniation following the chemonucleolysis procedure, but in the phase III clinical trial, the effective rate dropped to 72%. While the present study and the phase III trial used the same criteria, possible explanations for the decrease in effectiveness included differences in demographic data, frequency of female participants, mean age and type of hernia. Limitations in the present study included lack of RCT data and lack of long-term data.

Patients with lumbar disc herniation are often treated conservatively with surgery being the only therapeutic option available. Chiba et al. (2018) conducted a multicenter RCT at medical institutes in Japan to evaluate the effectiveness and safety of chemonucleolysis with condoliase in patients with lumbar disc herniation. One hundred and sixty-six participants were randomized into one of two groups either receiving the condoliase investigational drug or a placebo. The primary outcome was the change in leg pain, and this was measured by the VAS. The VAS was measured one week prior to the procedure, and again at weeks 13, 26, 29 and 52. Approximately 10% of the patients dropped out of the study and almost 10% of patients from each group underwent surgery following the study. Upon analysis of the VAS scores, the authors verified that the condoliase group had greater improvement in pain scores than the placebo group thus the condoliase group had significant clinical improvement. Limitations included exclusion of patients with disc herniation that included sequestration and transligamentous extrusions where condoliase may have been beneficial, lack of long-term follow-up with patients, and limited safety outcomes.

Houra et al. (2018) evaluated the safety and efficacy of percutaneous intervertebral disc chemonucleolysis for herniated disc. Over a 30-month period, 29 patients in three medical centers who failed conservative treatment for radicular pain received radiopaque gelified ethanol under fluoroscopic guidance. Only one patient received complete pain relief following the injection procedure; 18 patients received 50% pain relief over a six to twelve-month period. Four out of the 29 patients ended up having a surgical intervention due to complications of injection procedure or lack of pain relief. The authors concluded that while the treatment was safe and easy to handle, the gelified ethanol did not appear to be any more effective than microsurgery. It did however show a reduction in pain and disability as measured by the verbal numeric scale and Roland-Morris low back pain and disability questionnaire (RMQ). Limitations included small sample size with no control group.

A retrospective review on the efficacy of DiscoGel® for symptomatic disc herniation was conducted by Marcia and colleagues (2018). Inclusion criteria consisted of 71 patients with six months or more of back pain and resistant to conservative treatment. An MRI was performed on all participants to confirm one or more-disc herniations. Pain was evaluated by using the VAS) in addition to the functional ability score using the ODI; data was collected before the procedure and again at twelve months. All patients received local anesthesia and with fluoroscopic guidance 0.8 ml of DiscoGel® was injected into the nucleus pulposus for lumbar discs and 0.3 ml for cervical discs. Most levels treated were at the L4/L5 and/or L5/S1. The median VAS prior to the procedure averaged an eight whereas after the procedure it averaged a value of three. The average ODI score prior to the procedure was a 51 and afterwards was a fifteen. There was no significance difference between males and females in terms of pain scores. The authors found that DiscoGel® appeared to be a viable option for disc herniation however further prospective RCTs are warranted along with a larger population.

Feng et al. (2017) completed a meta-analysis of RCTs which compared the clinical results of seven types of surgical interventions: percutaneous endoscopic lumber discectomy (PELD), standard open discectomy (SOD), standard open microsurgical discectomy (SOMD), chemonucleolysis (CN), microendoscopic discectomy (MED), percutaneous laser disc decompression (PLDD), and automated percutaneous lumber discectomy (APLD).The authors compared success and complication rates of the procedures. From the seven procedures reviewed, PELD had the highest success rate and ALPD had the most complications followed by CN. The authors concluded that PELD might be the best choice for disc herniation surgery due to the best success rate and lowest complication rate. Additional high quality RCTs are needed to confirm these results.

A five-year follow-up assessment by Wittenberg et al. (2001) was completed for the use of chemonucleolysis with either chymopapain or collagenase. One hundred patients with intradiscal therapy were randomly assigned to receive one of the two enzyme treatments. Participant inclusion for the procedure consisted of patients that received six weeks or more of conservative therapy, sciatic leg pain was stronger than back pain, clear clinical signs for nerve root irritation, straight leg raises tested positive below 60 degrees, and radiologic findings by MRI or CT scan. Patients received the injection under fluoroscopic control and under general anesthesia. Following the injection procedure patients were closely monitored for two hours and then for another 24 hours. The patients were investigated clinically for segmental sensations, reflexes, and motor functions. Following discharge, patients were seen regularly for assessments at two, six, and twelve weeks and then at one, three and five-years. The results were graded into four categories: excellent, good, fair and poor. The authors found chymopapain was more effective than collagenase, however 18% of the chymopapain group and 28% of the collagenase group underwent microdiscectomy at the injected level within the first year after receiving the enzyme injections. Sixteen of the 100 patients were lost to follow-up. The authors concluded excellent results were achieved and not significantly different between the two enzymes, but the results from the chemonucleolysis was still worse than those observed after microdiscectomy. While chymopapain was shown to be reasonably safe, further studies are needed for collagenase.

Clinical trials for chemonucleolysis are ongoing and can be found at https://clinicaltrials.gov/ct2/home.
(Accessed August 29, 2023)

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.

Geudeke et al. (2021) conducted a systematic review and meta-analysis to evaluate the effectiveness of epiduroscopy in failed back surgery syndrome patients (FBSS). Of the 286 articles identified in PubMed, Embase, and Cochrane databases, nine studies were included. The VAS average was 7.6 at baseline, 4.5 at six months, and 4.3 at twelve months. The ODI average was 61.7% at baseline, 42.8% at six months, and 46.9% at twelve months. An average of 49% of patients experienced significant pain relief at six months and 37% at twelve months. Meta-analysis showed a pooled VAS mean difference of 3.4 (2.6 to 4.1; 95% confidence interval [CI]) and 2.8 (1.6 to 4.0; 95% CI) and pooled ODI mean difference of 19.4% (12.5 to 26.4%; 95% CI) and 19.8% (13.8 to 25.9%; 95% CI) at six months and twelve months, respectively. The authors concluded in FBSS patients, current literature demonstrates a clinically relevant reduction in disability scores and pain at six months to twelve months after mechanical adhesiolysis. The authors describe the quality of evidence as moderate, the level of recommendation as weak and recommend practitioners should weigh the benefits of epiduroscopy after considering the risk for individuals with FBSS. (Hazer et al. which was previously cited in this policy, is included in this systematic review and meta-analysis).

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 single U.S. hospital, 139 were available for evaluation at one 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 mono segmental or multisegmented 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 one year in both groups. The study is limited by lack of comparison group undergoing a different intervention.

Epidural Lysis of Adhesions (LOA)

Evidence in peer review literature evaluating epidural LOA for the diagnosis and/or treatment of spinal disorders is limited. Future robust RCT studies are warranted along with long-term outcomes to establish the safety and efficacy of this procedure.

Manchikanti et al. (2021) conducted a systematic review and meta-analysis on the role of percutaneous neurolysis in lumbar disc herniation. A search was conducted using the Cochrane review rating system and Interventional Pain Management Techniques – Quality Appraisal of Reliability and Risk of Bias Assessment Tool (IPM-QRB). A total of 6 trials (1 high quality RCT and 5 observational) were included in the review. The RCT from 2013 included 90 participants; the other 5 studies between 2015 and 2019 included 1,821 patients. Twelve-month results following the adhesiolysis/neurolysis procedure demonstrated 5 studies which displayed an improvement in NRS scores with an average score of 2.013, which was statistically significant and 2 studies that showed an improvement in the Oswestry Disability Index (ODI) functionality scores with an average score of 10.268 from a scale of 0-50. The authors did not find any significant side effects or complications. Limitations of this systematic review included lack of multiple RCTs, and the large-scale observational studies were of moderate quality.

A randomized, multi-center, double-blind trial was conducted by Gerdesmeyer et al. (2013, included in the Manchikanti (2021) systematic review above) to analyze the clinical efficacy of percutaneous epidural LOA in chronic radicular pain. Out of 381 patients with pain lasting longer than four months which failed to respond to conservative treatments, 90 individuals were enrolled. Participants were randomly assigned to receive either percutaneous neurolysis or placebo. The primary outcome measure was the differences in percent change of ODI scores three months post-procedure. The secondary outcome measure was 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 three, six, and twelve months in the lysis group vs the control group. The ODI in the lysis group improved from 55.3 to 26.4 after three months. The placebo group improved from 55.4 to 41.8. VAS improved from 6.7 to 2.9 in the active group and from 6.7 to 4.8 after placebo. Twelve-month follow-up showed 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. Gerdesmeyer et al. (2021) performed a 10-year follow-up study and found pain ratings of the treatment group were lower than ratings of the placebo group. The statistical difference of the ODI and VAS between the treatment and control groups remained significant up to ten years. Minor transient neurological effects were seen directly after the intervention, but no treatment-related severe adverse effects occurred within the ten years. The authors concluded the efficacy of the minimally invasive percutaneous adhesiolysis (PA) procedure for patients with chronic lumbosacral radicular pain was significant. Limitations noted by the authors include that the long-term effects of single treatment components cannot be specified as no imaging examination was performed at 10-year follow-up, a large variety of unanalyzed noninvasive treatments were done within the ten years, and some patients did not clearly remember the intervention after ten years. Additionally, uncontrolled effects such as higher in homogeneity of biometric properties, concomitant therapies, pain tolerance level, or just social effects could have occurred, but were not analyzed in the trial. A significant percentage of patients were lost to follow-up, but the percentage of these patients was balanced and similar in both groups.

Brito-García et al. (2019) assessed the efficacy, safety, effectiveness, and cost-effectiveness of epidural adhesiolysis for treating patients with chronic pain attributed to FBSS in a systematic review of the literature. Out of the studies that met the inclusion criteria, only two of them were RCTs which included a total of 212 participants; the other seven studies were observational. The authors assessed that even though the results from both RCTs had a favorable outcome for adhesiolysis, there was a high risk of bias and serious methodology flaws in the studies which included lack of blinding for participants, informing the participants of which treatment they had received and a high dropout rate. The observational studies were of low quality and did not provide any data indicating positive clinical development. The authors concluded the evidence on the efficacy and safety for adhesiolysis is insufficient in patients with FBSS and that further high quality RCTs should be done to assess for efficacy, effectiveness and cost.

A Hayes report reviewed percutaneous adhesiolysis (PA) for chronic LBP. The evidence base comprises six randomized controlled trials (RCTs) (seven publications, including one study with a longer-term follow-up study) and groups of 50-120 participants per study. The report concluded that a small body of low-quality evidence supports the use of PA for chronic LBP refractory to conservative treatment, including epidural steroid injections, given consistent findings of benefits in pain relief and

function compared with sham PA and epidural steroid injections, and a lack of serious complications in the evidence base. There is insufficient evidence pertaining to the comparison of adhesiolysis with physical therapy (PT) to draw definitive conclusions. However, it appears that in many cases, the adhesiolysis procedure must be repeated more than once a year to maintain its benefits. While the evidence suggests potential short- and intermediate-term efficacy of this procedure in patients with chronic LBP, whether or not epidural adhesions are the actual source of the pain in these patients has been debated, and long-term outcomes remain to be determined in well-designed trials. The report concludes that there is potential but unproven benefit for this approach (Hayes 2018; updated 2022).

Rapčan 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 chronic back surgery syndrome were randomized into two 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 six and twelve months via scheduled double-blinded examinations by pain physicians. Leg and back pain intensity were assessed by an 11-point numerical rating scale, and patients' functional disability was assessed by the ODI. Participants in both groups showed a significant decrease in ODI score as well as significantly lower scores for leg and back pain in both groups at six 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 one year. No significant difference between groups were observed. The authors concluded that while epiduroscopy with either standard treatment or drug therapy resulted in significant improvement of leg and back pain after six months, drug treatment was more durable for this study group.

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 PA. 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 two, four-, and twelve-weeks post-treatment. All the participants displayed epidural filling defects at baseline. After PA, 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 two weeks, respectively. There was no significant correlation between postprocedural VAS score and status of filling defects (yes or no) at three months. The author’s conclusion was that epidurographic findings following PA failed to correlate with level of pain reduction achieved in patients with degenerative lumbar spinal stenosis.

Lee et al. (2014) conducted a systematic review about epidural 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 RCTs. 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 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. Of the 21 studies identified, only four met inclusion criteria (one RCT and three observational studies). 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 twelve months or less, and long-term efficacy was twelve months or more. Using United States Preventive Services Task Force (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. In an update conducted three years later by Helm and associates (2016) the researchers evaluated the efficacy of PA 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, seven RCTs and three observational studies on PA met the inclusion criteria. For spinal endoscopy, there was one RCT and three 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 six months or less, and long-term efficacy was more than six months. The researchers concluded that PA 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.

There are open clinical trials studying epiduroscopy and epidural LOA for LBP. There are no trials identified studying these procedures for cervical spine conditions. For more information, go to www.clinicaltrials.gov. (Accessed August 31, 2023)

Clinical Practice Guidelines

American Association of Neurological Surgeons (AANS)/Congress of Neurological Surgeons (CNS)

In guidelines (Eck et al., 2014) regarding the use of discography in the evaluation of LBP prior to surgery, a joint committee of the AANS/CNS stated the following:

- Based primarily on retrospective studies, discography as a stand-alone test is not recommended to formulate treatment strategies for patients with LBP with abnormal imaging findings.
- A single randomized cohort study demonstrated an improved potential of discoblock over discography as a predictor of success following lumbar fusion. Therefore, discoblock should be considered as a diagnostic option during the evaluation of a patient presenting with chronic LBP.
- There is a possibility that an association exists between progression of degenerative disc disease and the performance of a provocative discogram. It is therefore recommended that patients be counseled regarding this potential development prior to undergoing discography.

American College of Radiology (ACR)

In the 2021 updated appropriateness criteria for patients with LBP, the ACR states that there is no relevant literature to support the use of discography for the following conditions:

- Acute uncomplicated LBP
- Evaluation of subacute or chronic LBP without red flags or prior management
- Initial imaging of suspected cauda equina syndrome (CES)
- Evaluation of new or progressing symptoms in patients with previous lumbar surgery
- Initial imaging for low back pain with or without radiculopathy for one or more of the following:
    - Low-velocity trauma, osteoporosis, elderly indivi0dual, or chronic steroid use
    - Suspicion of cancer, infection, or immunosuppression

American Society of Interventional Pain Physicians (ASIPP)

The Comprehensive Evidence-Based Guidelines for Interventional Techniques in Chronic Spinal Pain offers the following recommendations:

- Lumbar provocation discography is recommended with appropriate indications in patients with LBP to prove the diagnostic hypothesis of the discogenic pain specifically after exclusion of other sources of lumbar pain, only when a treatment is available.
- Cervical discography is indicated only when a treatment is available to test the diagnostic hypothesis of discogenic pain of the cervical spine in individuals who have been properly selected and screened to eliminate other sources of cervical pain.
- Thoracic discography can be performed to diagnose thoracic discogenic disease if the indication is appropriate and a treatment is available.
- Percutaneous adhesiolysis is recommended 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.

There are no recommendations for FAD. The use of anesthetic discography has generated significant interest as a means to reduce the high false-positive rates associated with provocation discography in certain patient subgroups. The ability of anesthetic discography used as either an adjunct or replacement for provocation discography, to enhance the accuracy of diagnosis, is mixed (Manchikanti et al., 2013).

In a 2018 systemic appraisal of the accuracy and utility of discography for chronic spinal pain, ASIPP states that PD performed according to International Association for the Study of Pain (IASP criteria) may be a useful tool for evaluating chronic lumbar discogenic pain. (Manchikanti et al., 2018).

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 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.

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Products such as endoscopes, catheters, and needles that can be used for epidural LOA are numerous. Refer to 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 August 21, 2023)

Products intended to help diagnose the cause of chronic LBP are numerous. Refer to 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 August 21, 2023)

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Policy History/Revision Information

Date	Summary of Changes
01/01/2024	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version 2023T0206Y

Instructions for Use

This Medical Policy 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 plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, 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 Policy is provided for informational purposes. It does not constitute medical advice.

This Medical Policy may also be applied to Medicare Advantage plans in certain instances. In the absence of a Medicare National Coverage Determination (NCD), Local Coverage Determination (LCD), or other Medicare coverage guidance, CMS allows a Medicare Advantage Organization (MAO) to create its own coverage determinations, using objective evidence-based rationale relying on authoritative evidence (Medicare IOM Pub. No. 100-16, Ch. 4, §90.5).

UnitedHealthcare may also use tools developed by third parties, such as the InterQual® criteria, to assist us in administering health benefits. UnitedHealthcare Medical Policies 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.