Policy Number	**SUR712.024**
Policy Effective Date	**05/15/2024**
Policy End Date	**12/31/2025**

Lysis of Epidural Adhesions

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Related Policies (if applicable)
None

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Coverage

Catheter-based techniques for lysis of epidural adhesions, with or without endoscopic guidance, **are considered experimental, investigational and/or unproven**. Techniques used either alone or in combination include mechanical disruption with a catheter and/or injection of hypertonic solutions with corticosteroids, analgesics, or hyaluronidase.

Policy Guidelines

Protocols for lysis of epidural adhesions vary. The following codes may be used to describe lysis of adhesions:

- There is no specific code for endoscopic lysis of epidural adhesions therefore unlisted code 64999 is used.
- CPT 62263 describes the percutaneous insertion using a solution injection.
- CPT 62264; as noted above but limited to 1 day only.
- There is instruction following CPT 77003 that states 62263 and 62264 includes fluoroscopic guidance and localization.

- Lysis of epidural adhesions using hypertonic saline may be offered as a component of a multimodality pain management program.

Description

Lysis of epidural adhesions involves passing a catheter, either endoscopically or percutaneously, under fluoroscopic guidance into the epidural space to break up adhesions and reduce pain and inflammation.

Background

Epidural Fibrosis and Adhesive Arachnoiditis

Epidural fibrosis with or without adhesive arachnoiditis most commonly occurs as a complication of spinal surgery and may be included under the diagnosis of "failed back surgery syndrome". Both conditions result from the manipulation of the supporting structures of the spine. Epidural fibrosis can occur in isolation, but adhesive arachnoiditis is rarely present without associated epidural fibrosis. Arachnoiditis is most frequently seen in patients who have undergone multiple surgical procedures.

Epidural fibrosis and adhesive arachnoiditis are related to inflammatory reactions that result in the entrapment of nerves within dense scar tissue, increasing the susceptibility of the nerve root to compression or tension. The condition most frequently involves the nerves within the lumbar spine and cauda equina. Signs and symptoms indicate the involvement of multiple nerve roots and include low back pain, radicular pain, tenderness, sphincter disturbances, limited trunk mobility, muscular spasm or contracture, and motor-sensory and reflex changes. Typically, pain is characterized as constant and burning. In some cases, pain and disability are severe, leading to analgesic dependence and chronic invalidism.

Treatment

Lysis of epidural adhesions, also called the Racz procedure, has been investigated as a treatment option. The Racz procedure involves the passage of a fluoroscopically guided catheter (the Racz catheter), inserted either endoscopically or percutaneously, and the use of epidural injections of hypertonic saline in conjunction with corticosteroids and analgesics. Theoretically, the use of hypertonic saline results in mechanical disruption of the adhesions. The saline may also function to reduce edema within previously scarred and/or inflamed nerves. Finally, manipulating the catheter at the time of the injection may disrupt adhesions. Spinal endoscopy has been used to guide the lysis procedure, but the procedure is more commonly performed percutaneously using epidurography to guide catheter placement and identify nonfilling adhesions that indicate epidural scarring. Using endoscopy guidance, a flexible fiberoptic catheter is inserted into the sacral hiatus, providing 3-dimensional visualization to steer the catheter toward the adhesions. With the increased visualization, the catheter is more apt to precisely place the injectate in the epidural space and onto the nerve root. Various protocols for lysis have been described; in some situations, the catheter may remain in place for several days for serial treatment sessions.

Endoscopic epidurolysis is also being investigated to treat degenerative chronic low back pain, including spondylolisthesis, stenosis, and hernia associated with radiculopathy. Along with mechanical adhesiolysis, hyaluronidase, ciprofloxacin, and ozone have been applied.

Regulatory Status
Lysis of epidural adhesions is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration (FDA).

Rationale

This medical policy was created in November 2000 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through February 7, 2024.

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

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

Lysis
The evidence for lysis of epidural adhesions consists of single-center trials, most of them from a single pain management group.

Clinical Context and Therapy Purpose
The purpose of lysis in individuals who have epidural adhesions is to provide a treatment option that is an alternative to or an improvement on existing therapies.

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

Populations
The relevant population of interest is individuals with epidural adhesions.

Interventions
The therapy being considered is lysis.

Lysis is a surgical procedure generally administered in an inpatient hospital setting under conscious sedation using imaging guidance.

Comparators
The following practice is currently being used to treat lysis: medical management.

Outcomes
The general outcomes of interest are reductions in symptoms (e.g., pain severity) and medication use, improvement in functional improvement, and treatment-related adverse events (e.g., neurologic deficits).

Postsurgical follow-up can range from six to eight weeks.

Systematic Reviews
Manchikanti et al. (2023) published a systematic review and examined nine randomized controlled trials investigating the efficacy of percutaneous adhesiolysis in managing low back pain between 1966-2022. (1) Researchers examined pain level following procedure, functionality using the Oswestry Disability Index (ODI), Opioid consumption, at three, six, and twelve months. Pain level at three, six, and twelve months was statistically different compared to control in all but one study. Functionality was also significantly different compared to control at three, six, and twelve in all but two studies. Opioid consumption between control and treatment was statistically significant in 2/9 studies at three months, 3/9 studies at six months, and 3/9 studies at 12 months. Overall, the authors suggest that percutaneous adhesiolysis is effective in managing low back pain, however the findings are significantly limited. This analysis only includes symptom reporting up to twelve months and does not include any long-term side effects possibly associated with this procedure. Additionally, the majority of these studies include a relatively small sample size ranging from 25-120 patients. Other RCTs of lysis of epidural adhesions have been published; however, these trials have significant methodological limitations, such as small sample size and/or short duration of follow-up. Limitations of this review include the paucity of literature despite nine eligible trials that looked at various conditions separately. The other limitation is the lack of placebo-controlled trials despite significant differences noted among the active-controlled trials utilizing epidural injection as control.

Manchikanti et al. (2021) conducted a systematic review and meta-analysis on the role of percutaneous neurolysis in lumbar disc herniation. (2) Multiple databases were searched from

1966 to January 2021. A total of 6 trials (1 high quality RCT and 5 moderate-quality non-randomized) were included in the review. The primary outcome measure was the proportion of patients with significant pain relief and functional improvement (≥ 50%). Duration of relief was categorized as short term (< 6 months) and long-term (≥ 60 months). Reference point measurements were considered at 3, 6, and 12 months. The RCT from 2013 included 90 participants; the other 5 studies between 2015 and 2019 included 1,821 patients. At twelve months, the results following the adhesiolysis/neurolysis procedure demonstrated 5 studies which displayed a significantly significant improvement in numeric rating scale (NRS) scores (average score of 2.013), 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. No significant side effects or complications from these studies were identified. This systematic review was limited by the lack of multiple RCTs, and the moderate quality of the observational studies.

In a 2021 systematic review and meta-analysis, Geudeke et al. (2021) evaluated the effectiveness of epiduroscopy in failed back surgery syndrome (FBSS) patients. (3) From the 286 identified articles, nine studies were included. The visual analogue scale (VAS) average was 7.6 at baseline, 4.5 at 6, and 4.3 at 12 months. The Oswestry Disability Index (ODI) average was 61.7% at baseline, 42.8% at 6, and 46.9% at 12 months. An average of 49% of patients experienced significant pain relief at 6 and 37% at 12 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 6 and 12 months, respectively. Reviewers concluded that although the current literature demonstrates a clinically relevant reduction in pain and disability scores at 6 to 12 months after mechanical adhesiolysis in FBSS patients, the quality of evidence is moderate, and the level of recommendation is weak. Practitioners should consider the benefits of epiduroscopy after weighing the risks for individual patients with FBSS.

In 2019, Brito-Garcia et al. conducted a systematic review to evaluate the efficacy, effectiveness, safety, and cost-effectiveness of epidural adhesiolysis compared with other procedures for treating FBSS. (4) Ten reports were included. No RCTs on efficacy or cost-effectiveness were found. Three reports (corresponding to two RCTs, N = 212) suggested that adhesiolysis was effective, especially for pain and disability. However, both studies presented serious methodological flaws. In addition to RCTs, seven observational studies with high risk of bias reported data on effectiveness and safety. Fifty-eight adverse events were reported among 130 patients undergoing endoscopic adhesiolysis, and 19 among the 110 undergoing percutaneous adhesiolysis. Reviewers concluded that the evidence on the efficacy and cost-effectiveness of adhesiolysis for treating FBSS is nonexistent, whereas evidence on its effectiveness and safety is insufficient. Incorporating data from observational studies did not improve the quality of the evidence on effectiveness.

Manchikanti et al. (2019) performed a systematic review of RCTS and observational studies assessing the role of percutaneous adhesiolysis in managing lumbar central spinal stenosis. (5) The primary outcome or hard endpoint was defined as the proportion of patients with 50% pain

relief and improvement in functionality, whereas the secondary outcome measures or soft endpoints were pain relief and/or improvement in functionality. Short-term effectiveness was defined as improvement of 6 months or less, whereas long-term effectiveness was defined as more than 6 months. Based on search criteria, 9 manuscripts were identified and considered for inclusion with final inclusion of 2 RCTs and 4 observational studies in this systematic review and 5 studies for single arm meta-analysis. While the authors graded the evidence at Level II for short-term and long-term improvement in pain and function with application of percutaneous adhesiolysis in managing central lumbar spinal stenosis, there were a number of limitations, such as the small number of included studies in each analysis, and the same primary author for the meta-analysis, one of the included studies, and the tool used to grade the evidence.

A systematic review on endoscopic adhesiolysis by Helm et al. (2013) included an RCT and 3 observational studies and noted there was a limited amount of literature on endoscopic adhesiolysis. (6) Despite limitations in available evidence, using U.S. Preventive Services Task Force (USPSTF) quality of evidence criteria, reviewers concluded there was fair evidence that spinal endoscopic adhesiolysis is effective in reducing chronic low back and/or leg pain in post lumbar surgery syndrome in both the short- and long-term (>12 months).

Hayek et al. (2009) concluded that, based on level II-1 or II-2 evidence (1 randomized trial, 5 observational studies), endoscopic adhesiolysis provides short- and long-term relief of pain based on the USPSTF criteria. (7) Epter et al. (2009) (8) with Hayek et al. (2009) (7) and others concluded that there was level I or II evidence (3 randomized trials, 4 observational studies) for percutaneous adhesiolysis.

In a review, Racz et al. (2008) concluded, based on the literature (randomized trials and case series) and expert opinion, that evidence was strong for short-term (3 months) efficacy and moderate for long-term (>3 months) efficacy. (9)

A review by Chopra et al. (2005) (10) focused on 3 randomized studies by Heavner and Manchikanti and concluded that there was moderate-to-strong evidence of the effectiveness of percutaneous adhesiolysis. A 2007 update of that review also concluded that there was strong evidence for short-term and moderate evidence of long-term effectiveness of percutaneous adhesiolysis and spinal endoscopy. (11) Applying the USPSTF criteria, a 2012 update of the review found fair evidence that percutaneous adhesiolysis is effective in relieving low back and/or leg pain caused by post lumbar surgery syndrome or spinal stenosis. (12) Complications were considered to be minimal.

The primary studies cited in these reviews were assessed individually for this medical policy (see following sections).

<u>Percutaneous Lysis of Adhesions Without Spinal Endoscopy</u>

Randomized Controlled Trials

Vigneri et al. (2021) evaluated sural nerve conduction and Hoffmann reflex (H-reflex) in soleus muscle following adhesiolysis and pulsed radiofrequency (PRF) in patients with unilateral

chronic lumbosacral L5-S1 neuropathic radiating pain. (13) Seventeen patients received two cycles of 240 seconds high-voltage PRF and epidural adhesiolysis. Sural nerve action potential (SNAP) and the ratio of maximum H-reflex to maximum M response (H/M ratio) as well as pain scores were collected in both lower limbs before, immediately following, and 1 month after the treatment. At follow-up, a significant reduction in numeric rating scale (NRS) and Douleur Neuropathique 4 Questions (DN4) scores was observed in 53% of patients reporting pain improvement of ≥ 30% over baseline. The H/M ratio was decreased in the affected limb following PRF (P = 0.01) and 1 month after the treatment (P = 0.04). A direct correlation was observed between H/M ratio variation and NRS score at follow-up in the treated limb (P = 0.04). No significant difference in sural nerve latency, amplitude, and velocity was detected between affected and normal side after treatment and at follow-up. Researchers concluded that epidural adhesiolysis and PRF of the dorsal root ganglion seem to significantly affect spinal reflexes in patients with lumbosacral neuropathic radiating pain. However, there were several limitations including the lack of blinding, control comparison, limited sample size, and the use of the DN4 questionnaire which has not been validated for radicular pain.

Gerdesmeyer et al. (2013) reported on a randomized, double-blind, placebo-controlled trial assessing percutaneous epidural lysis of adhesions for chronic lumbar radicular pain at 4 participating treatment centers. (14) Of 381 patients screened, 90 patients were randomized in permuted blocks of 4 to 8 to adhesiolysis or placebo. Eligible patients had chronic lumbosacral radicular pain after disc protrusion or after failed back surgery and had completed at least four months of unsuccessful conservative treatment. Patients in both groups (adhesiolysis and placebo) received injections on each of three days and physical therapy after the series of injections. In the adhesiolysis group, the day 1 injection consisted of 10 mL saline with 150 U/mL hyaluronidase, plus 10 mL saline with 40 mg triamcinolone and 2 mL of 0.25% bupivacaine; this initial injection was followed by day 2 and 3 injections of saline with an anesthetic. The placebo group received saline injections each of the three days through a catheter placed over the affected area but not into the spinal canal. After 3 months, the ODI score significantly improved in the adhesiolysis group (55.3 to 26.4) compared with the placebo group (55.4 to 41.8; p<0.01). After three months, the VAS score was also significantly improved in the adhesiolysis group (6.7 to 2.9) compared with the placebo group (6.7 to 4.8; p<0.01]). ODI and VAS scores remained significantly more improved in the adhesiolysis group than the control group at 6 and 12 months. In the adhesiolysis group, more patients experienced pain during the intervention and transient neurologic deficits (numbness, paralysis, motor weakness) after the intervention than in the control group (34 vs 20 and 42 vs 6, respectively). All neurologic deficits resolved during hospitalization. Limitations of this trial included failure to place the catheter near the anterolateral epidural space of the targeted pathology, and the unknown effect of each component of treatment. The large effect seen in the placebo group also brings into question whether the placement of the catheter in the subcutaneous tissue produces a beneficial effect.

Ten-year follow-up results from this study were published by Gerdesmeyer in 2021. (15) While the statistical difference of the ODI and VAS between the treatment and control groups remained significant up to 10 years, there were a number of limitations: 1) The long-term

effects of single treatment components could not be specified as no imaging examination was performed at 10 year follow-up; 2) A large variety of unanalyzed noninvasive treatments were done within the 10 years; 3) Some patients did not clearly remember the intervention after 10 years; 4) Uncontrolled effects such as higher inhomogeneity of biometric properties, concomitant therapies, pain tolerance level, or just social effects could occur, but were not analyzed in the trial.

Two comparative effectiveness RCTs by Manchikanti et al. (2009) reported on 1-year outcomes. (16, 17) Patients in 1 trial had FBSS (planned enrollment, 200 patients), and patients in the other had chronic low back pain (planned enrollment, 120 patients). The comparator in both trials was epidural corticosteroid injection. In both trials, the procedure in the intervention group included epidurography, the introduction of the Racz catheter to the level of defect, adhesiolysis and/or targeted catheter positioning, repeat epidurography with confirmation of ventral and lateral filling, and injection of lidocaine. After all the procedures were performed, patients received an injection of 10% sodium chloride solution and an injection of betamethasone. The control group received epidurography, the introduction of the catheter up to S3 or S2, repeat epidurography, injection of lidocaine, and injection of normal saline and betamethasone. For the patients with failed back surgery, significant pain relief (defined as >50% reduction in VAS score) was achieved by 73% of patients in the lysis group compared with 12% in the control group ($p<0.001$). For patients with spinal stenosis, there were no outcomes reported at the time of publication. In the 2-year follow-up report on the study with 120 patients treated for chronic low back pain, Manchikanti et al. (2012) reported 82% of patients receiving adhesiolysis had significant improvement in functional status and relief of pain of at least 50% compared with only 5% improvement in the epidural corticosteroid injection group. (18) If patients had improved functioning and reduced pain by at least 50% for at least 3 months following adhesiolysis, repeat adhesiolysis was permitted. Patients in the adhesiolysis group received an average of 6.4 adhesiolysis procedures while patients in the epidural corticosteroid injection group averaged 2.4 procedures over the two-year period.

A number of limitations are apparent in these trials. Losses to follow-up in the control groups were large in both studies (10/60 at 6 months, 43/60 at 12 months, 52/60 at 2 years in the failed back surgery study; 10/25 at 6 months, 18/25 at 12 months in the spinal stenosis study). There were few dropouts in the intervention groups. Thus, differential loss in follow-up is a major concern. Patients received additional treatments if needed (criteria for repeat treatment not given), and the type of treatment was based on the response to the previous injections, either after unblinding or without unblinding. Physicians performing procedures could not be blinded to the treatment group, but they did not know which patients were participating in the studies.

Several earlier, smaller, randomized trials were reported by Manchikanti and colleagues. Manchikanti et al. (2004) published the results of a trial that randomized 75 patients to 1 of 3 groups, either a control group consisting of catheterization without adhesiolysis or to adhesiolysis with or without additional hypertonic saline. (19) All patients received epidural injections of local anesthetic and corticosteroids. Significant differences in pain relief, ODI

scores, and range of motion were noted between the two treatment groups and the control group. In another trial, Manchikanti et al. (2001) randomized 45 patients to a 1- or a 3-day course of lysis of epidural adhesions. (20) A total of 97% of the treatment group with 1 to 3 injections reported at least 50% pain relief at 3 months, which fell to 93% at 6 months, and to 47% at 1 year. There were no significant improvements in the control group.

Prospective and Retrospective Studies

Serious adverse events from epidural lysis have been reported. (21) Manchikanti et al. (2012) reported on a prospective observational study of complications in 10000 fluoroscopically directed epidural injections, including more than 800 cases treated by percutaneous adhesiolysis at their institution. (22) Measured outcomes included intravascular entry of the needle, profuse bleeding, local bleeding, local hematoma, bruising, dural puncture and headache, nerve root or spinal cord irritation, infection, numbness, postoperative soreness, and increased pain. There was an intravascular entry in 11.6% of adhesiolysis cases, return of blood in 3.6%, transient nerve root irritation in 1.9%, and dural puncture in 1.8% of cases. Other complications occurred in less than 1% of cases. There were no major complications in this cohort.

Kim et al. (2023) published a retrospective study examining patients with low back pain who underwent lumbar epidural adhesiolysis. (23) Participants were followed for at least six months with follow-up at one, three, and six months. Of the 169 participants enrolled, 77 patients (45%) reported clinically meaningful pain relief (defined as >30% pain reduction at six month follow-up), and 92 patients (54%) reported poor pain relief after adhesiolysis. The number of patients with a pain duration of <3 months, 3 months-1 year, 1-3 years, and >3 years were 52 (30.8%), 56 (33.1%), 35 (20.7%), and 26 (15.4%), respectively. The majority of patients who had a longer pain duration (>3 years) prior to the procedure had higher graded lumbar central stenosis on MRI, and reported poor pain relief six months following the procedure (80.8%). Limitations of this study include its retrospective design in a single center, and that most patients were already using pain medication or had previously received some injection therapies. These findings do not support the use of epidural adhesiolysis as most patients had poor pain relief following the procedure.

Subsection Summary: Percutaneous Lysis of Adhesions Without Spinal Endoscopy

Several RCTs have reported benefits for epidural lysis of adhesions compared with placebo treatment. The interpretation of these trials is limited by differences in patients, populations, and treatment protocols. The treatment for lysis of adhesions varied in the use of mechanical disruption, the type of lytic medications used, and the number of injections given. There was also a large effect seen in the placebo group, raising questions whether some components of the placebo treatment may be therapeutic. Larger trials with standardized treatment protocols would be helpful in determining whether specific treatment protocols have beneficial effects in specific patient populations.

Percutaneous Lysis of Adhesions with Spinal Endoscopy

Randomized Controlled Trials

Rapcan et al. (2018) compared the efficacy of drugs (the enzyme hyaluronidase and corticosteroid DEPO-Medrol) administrated into the epidural space during epiduroscopy, performed within the ventral and ventro-lateral epidural space with a focus on releasing foraminal adhesions. (24) Forty-eight patients with diagnosed FBSS were randomized into two groups before epiduroscopy. Group A received the standard treatment-mechanical lysis of fibrotic tissue in the epidural space. Group B received hyaluronidase and corticosteroid methylprednisolone acetate during the procedure. Subjects were followed for six 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. Study subjects showed a significant decrease in ODI score in both groups ($P < 0.05$). Significantly lower pain scores for leg pain ($P < 0.05$) and back pain ($P < 0.05$) were also recorded after the six-month follow-up. However, the one-year follow-up showed a return to the baseline ODI values of most monitored pain scores in both groups ($P > 0.05$). Improvement was only noted on the numerical rating scale (NRS) for back pain at one-year follow-up ($P < 0.05$). 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.

One small RCT was identified by Manchikanti et al. (2003). (25) Twenty-three patients with back pain of greater than six months in duration were randomized to spinal endoscopy followed by injection of local anesthetic or corticosteroid (control group) or the above procedure plus lysis of adhesions with normal saline and mechanical disruption with the fiberoptic endoscope. The trial was double-blinded. Patient selection criteria included failure of conservative management, including failure of prior attempts at lysis of adhesions using hypertonic saline. The principal outcomes included changes in VAS and ODI scores at six months. In the control group, the mean VAS score dropped from 8.7 at baseline to 7.6 at 6 months, while the scores in the intervention group dropped from 9.2 at baseline to 5.7 at six months. The difference between groups was statistically significant. There was also a significant difference between groups in the percentage of patients experiencing at least a 50% reduction in pain. Blinding appeared to be successful because 6 of the 16 patients in the control group believed they were in the intervention group, and 8 of 23 patients in the intervention group believed they were in the control group. While this trial reported promising results, its small size limits interpretation.

Prospective and Retrospective Studies

Hong Park et al. (2017) conducted a prospective study of 78 patients with degenerative lumbar spinal stenosis (LSS) to assess the relationship between improvement shown on epidurogram and subjective patient response after undergoing percutaneous adhesiolysis. (26) Each subject underwent magnetic resonance imaging of the lumbar spine, with all therapeutic procedures conducted in the operating room. Two weeks later, a second epidurography was performed. Second epidurography was conducted to assess any change in epidural filling defects. Outcome measures were obtained using the VAS score at two weeks, one month, and three months post-

treatment. All of the 78 study participants (mean age = 60.9 years, range = 34–85 years) 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, respectively, at two weeks' follow-up. No significant correlation between postprocedural VAS score and status of filling defects (yes or no) was evident during the three-month follow-up period. Researchers concluded that in patients with LSS, epidurographic findings following percutaneous epidural adhesiolysis failed to correlate with level of pain reduction achieved.

Donato et al. (2011) reported a 48-month follow-up from a prospective case series of 234 patients with chronic low back pain due to FBSS, spondylolisthesis, stenosis, or hernia. (27) In addition to the 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. Significant improvements in VAS and ODI scores were reported throughout the 48-month follow-up. Adverse events included 32 (13.7%) patients who had sacral pain lasting at least 2 weeks and 13 (5.5%) patients who experienced nonpainful paresthesia and subsequently underwent surgical intervention. This study has a number of limitations, including the lack of information on the number of patients available for long-term follow-up and the lack of a control group.

Two other retrospective studies by Manchikanti et al. (1999, 2000) have examined outcomes for patients who underwent lysis with (n=120) or without (n=60) adjunctive endoscopy. (28, 29) Because these articles were coauthored by the same investigator, it is likely that they included overlapping patients. These studies also did not include a control group, and thus clinical conclusions regarding the contribution of endoscopy are not possible.

Summary of Evidence

For individuals who have epidural adhesions who receive lysis, the evidence includes prospective and retrospective studies, as well as randomized controlled trials (RCTs). The relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Several RCTs have reported benefits for epidural lysis of adhesions compared with placebo treatment. Many of these trials were conducted at the same center. The interpretation of these trials is limited by differences in patients, populations, and treatment protocols. The treatment for lysis of adhesions varied in the use of mechanical disruption, the type of lytic medications used, and the number of injections given. There was also a large effect in the placebo group, raising questions whether some components of the placebo treatment may be therapeutic. Larger trials with standardized treatment protocols would help determine whether specific treatment protocols have beneficial effects in specific patient populations. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

American Society of Interventional Pain Physicians

In 2013, the American Society of Interventional Pain Physicians updated its practice guidelines on the management of chronic spinal pain. (30) The guidelines stated that “for lumbar percutaneous adhesiolysis, the evidence is fair in managing chronic low back and lower extremity pain secondary to post surgery syndrome and spinal stenosis.” Percutaneous adhesiolysis was recommended, “after failure of conservative management of physical therapy, chiropractic, drug therapy, structured exercise program, and fluoroscopically directed epidural injections.” The guidelines also indicated that spinal epidural endoscopic adhesiolysis was not discussed because there is limited evidence; moreover, the procedure is rarely used. The studies cited in the guidelines were evaluated for this medical policy.

National Institute for Health and Care Excellence (NICE)

In 2010, NICE issued guidance on therapeutic endoscopic division of epidural adhesions, offering the following (31):

- " 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. "

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in February 2024 did not identify any ongoing or unpublished trials that would likely influence this policy.

Coding

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

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

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

CPT Codes	62263, 62264, 64999
HCPCS Codes	J7131

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

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

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

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

Policy History/Revision

Date	Description of Change
05/15/2024	Document updated with literature review. Coverage unchanged. Added references 1, 2, 23, and 31.
06/01/2023	Reviewed. No changes.
12/01/2022	Document updated with literature review. Coverage unchanged. Added references 1, 11 and 13.
02/01/2022	Reviewed. No changes.
10/01/2021	Document updated with literature review. Coverage unchanged. Added the following references: 1, 2, 18 and 20.
01/15/2021	Reviewed. No changes.
08/15/2020	Document updated with literature review. Coverage unchanged. No new references added.
01/15/2020	Reviewed. No changes.
02/15/2019	Document updated with literature review. Coverage unchanged. No references added or removed.
03/15/2018	Reviewed. No changes.
03/01/2017	Document updated with literature review. Coverage unchanged.
04/15/2016	Reviewed. No changes.
09/15/2015	Document updated with literature review. Coverage changed to: Catheter-based techniques for lysis of epidural adhesions, with or without endoscopic guidance, are considered experimental, investigational and /or unproven.

	Techniques used either alone or in combination include mechanical disruption with a catheter and/or injection of hypertonic solutions with corticosteroids, analgesics, or hyaluronidase.
02/01/2015	Document updated with literature review. Coverage unchanged. Titled changed from Percutaneous Lysis of Epidural Adhesions.
01/01/2013	Document updated with literature review. Coverage unchanged. This document is no longer scheduled for routine literature review and update.
11/15/2010	Document updated with literature review. Coverage unchanged.
01/01/2009	New CPT/HCPCS code(s) added
03/01/2008	Revised/updated entire document
02/01/2006	Coverage Revised
07/15/2004	Revised/updated entire document
11/01/2000	New Medical Document