

# Medical Policy



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## Title: Lysis of Epidural Adhesions

### Professional

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Populations	Interventions	Comparators	Outcomes
Individuals: • With epidural adhesions	Interventions of interest are: • Lysis	Comparators of interest are: • Medical management	Relevant outcomes include: • Symptoms • Functional outcomes • Quality of life • Medication use • Treatment-related morbidity

**DESCRIPTION**

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

**OBJECTIVE**

The objective of this policy is to determine whether the use of epidural injections for lysis of adhesions—either by using hypertonic saline alone or by using hypertonic saline in combination with corticosteroids, analgesics, or mechanical disruption—improves the net health outcome.

**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 result from 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, the pain is characterized as constant and burning. In some cases, the 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 injection of hypertonic saline in conjunction with corticosteroids and analgesics. Theoretically, the use of hypertonic saline results in a mechanical disruption of the adhesions. It 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-D 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 for the treatment of 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.

### **POLICY**

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

### **RATIONALE**

The most recent literature search was performed through September 14, 2018. Following is a summary of the literature to date.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are 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 to 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 a technology, 2 domains are examined: the relevance and the 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 U.S. pain management group.

Clinical Context and Therapy Purpose

The purpose of lysis in patients who have epidural adhesions is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of lysis improve the net health outcome in patients with epidural adhesions?

The following PICOTS were used to select literature to inform this review.

Patients

The relevant population of interest is individuals with epidural adhesions.

Interventions

The therapy being considered is lysis.

Comparators

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

Outcomes

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

Timing

Postsurgical follow-up can range from 6 to 8 weeks.

Setting

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

Systematic Reviews

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.<sup>1</sup> 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.<sup>2</sup> Epter et al (2009) with Hayek and others concluded that there was level I or II evidence (3 randomized trials, 4 observational studies) for percutaneous adhesiolysis.<sup>3</sup>

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.<sup>4</sup>

A review by Chopra et al (2005)<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup> Complications were considered to be minimal.

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

### Percutaneous Lysis of Adhesions Without Spinal Endoscopy

#### Randomized Controlled Trials

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.<sup>8</sup> 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 4 months of unsuccessful conservative treatment. Patients in both groups (adhesiolysis and placebo) received injections on each of 3 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 anesthetic. The placebo group received saline injections each of the 3 days through a catheter placed over the affected area but not into the spinal canal. After 3 months, the Oswestry Disability Index (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 3 months, the visual analog scale (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 placement of the catheter in the subcutaneous tissue produces a beneficial effect.

Two comparative effectiveness RCTs by Manchikanti et al (2009) reported on 1-year outcomes.<sup>9,10</sup> Patients in 1 trial had failed back surgery syndrome (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, 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 procedures were performed, patients received an injection of 10% sodium chloride solution and an injection of betamethasone. The control group received epidurography, 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.<sup>11</sup> 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 2-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 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.<sup>12</sup> 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 2 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.<sup>13</sup> 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 Studies

Serious adverse events from epidural lysis have been reported.<sup>14</sup> Manchikanti et al (2012) reported on a prospective observational study of complications in 10,000 fluoroscopically directed epidural injections, including more than 800 cases treated by percutaneous adhesiolysis at their institution.<sup>15</sup> 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.

*Section 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 component 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 EndoscopyRandomized Controlled Trials

One small RCT was identified by Manchikanti et al (2003).<sup>16</sup> Twenty-three patients with back pain of greater than 6 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 6 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 6 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

Donato et al (2011) reported 48-month follow-up from a prospective case series of 234 patients with chronic low back pain due to failed back surgery syndrome, spondylolisthesis, stenosis, or hernia.<sup>17</sup> In addition to mechanical removal of adherences, targeted ozone, hyaluronidase, and ciprofloxacin were applied. Efficacy was prospectively evaluated by an independent investigator at 1 week and 3, 6, 12, 24, 36, and 48 months. 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 a 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.<sup>18,19</sup> 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 randomized controlled trials. 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 component 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

The American Society of Interventional Pain Physicians updated their practice guidelines on the management of chronic spinal pain in 2013.<sup>20</sup> The guideline states 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 is recommended "after failure of conservative management of physical therapy, chiropractic, drug therapy, structured exercise program, and fluoroscopically directed epidural injections." The guideline also states spinal epidural endoscopic adhesiolysis is not discussed since there is limited evidence and the procedure is rarely used. The studies cited in the guideline have been reviewed for this evidence review.

#### American Pain Society

The American Pain Society's 2009 clinical practice guidelines on interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain did not discuss or draw conclusions on adhesiolysis.<sup>21</sup> The guidelines stated that "for other interventions or specific clinical circumstances, the panel found insufficient evidence from randomized controlled trials to reliably judge benefits or harms."

### **U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATION**

Not applicable.

### **ONGOING AND UNPUBLISHED CLINICAL TRIALS**

Some currently unpublished trials that might influence this review are listed in Table 1.

**Table 1.** Summary of Key Trials

<b>NCT No.</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date</b>
<b>Unpublished</b>			
NCT01053572 <sup>a</sup>	Evaluation of the Role of Steroids and 10% Hypertonic Sodium Chloride in Adhesiolysis in Post Lumbar Surgery Syndrome Patients: A Prospective, Randomized, Double-Blind, Equivalence, Controlled Trial of Percutaneous Lumbar Adhesiolysis	240	Jan 2014 (completed)
NCT01053273 <sup>a</sup>	Comparative Effectiveness of Percutaneous Adhesiolysis and Caudal Epidural Steroid Injections in Low Back and/or Lower Extremity Pain: A Randomized, Equivalence Trial	120	Jan 2014 (completed)

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

**CODING**

**The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.**

**CPT/HCPCS**

- 62263 Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 2 or more days
- 62264 Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 1 day

**DIAGNOSIS**

Experimental / Investigational for all diagnoses related to this medical policy.

**REVISIONS**

02-08-2010	The Lysis of Epidural Adhesions medical policy is a new freestanding policy developed from the Minimally Invasive Procedures for Spine Pain medical policy which was effective October 18, 2004. The Minimally Invasive Procedures for Spine Pain is no longer an active medical policy.
01-01-2012	In the Coding section: <ul style="list-style-type: none"> <li>▪ Removed HCPCS code: J7130</li> <li>▪ Added HCPCS code: J7131</li> </ul> Updated the Reference section.
03-28-2012	Updated Rationale section. Updated Reference section.
03-13-2013	Updated Rationale section. Updated Reference section.
08-15-2014	In the Coding Section: <ul style="list-style-type: none"> <li>▪ Removed HCPCS code: J7131</li> <li>▪ Added HCPCS code: J7130</li> <li>▪ Removed reference to ICD-9 codes 349.0-349.9</li> </ul> Updated Rationale section. Updated Reference section.
02-16-2015	Updated Description section. Updated Rationale section. In Coding section: <ul style="list-style-type: none"> <li>▪ Removed HCPCS code: J7130</li> </ul>
02-17-2016	Updated Description section. Updated Rationale section. Updated References section.
04-25-2018	Updated Description section. Updated Rationale section. Updated References section.

01-16-2019	Updated Description section.
	Updated Rationale section.
	Updated References section.

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