

# *Effective February 26, 2018 Policy Replaced by LCD L36954*



BlueCross BlueShield  
of Alabama

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## **Name of Blue Advantage Policy: Lysis of Epidural Adhesions**

Policy #: 420  
Category: Therapy

Latest Review Date: November 2017  
Policy Grade: B

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### **Background:**

*Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational\*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
  - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
  - *Furnished in a setting appropriate to the patient's medical needs and condition;*
  - *Ordered and furnished by qualified personnel;*
  - *One that meets, but does not exceed, the patient's medical need; and*
  - *At least as beneficial as an existing and available medically appropriate alternative.*

*\*Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare** for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

## **Description of Procedure or Service:**

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

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 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.

Both conditions 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.

Lysis of epidural adhesions, also called the Racz procedure, involves passage of a catheter (Racz catheter) endoscopically or percutaneously, using fluoroscopic guidance, with epidural injections of hypertonic saline in conjunction with corticosteroids and analgesics, has been investigated as a treatment option. 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 non-filling adhesions that indicate epidural scarring. Prior to the use of endoscopy, adhesions can be identified as non-filling lesions on fluoroscopy. Using endoscopy guidance, a flexible fiberoptic catheter is inserted into the sacral hiatus, providing 3-D visualization to steer the catheter toward the adhesions, to more 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.

## **Policy:**

**Effective for dates of service on or after February 26, 2018 refer to LCD L36954**

**Effective for dates of service on or after January 11, 2011 and prior to February 26, 2018:**

**Blue Advantage** will treat **catheter-based techniques for lysis of epidural adhesions**, with or without endoscopic guidance, as a non-covered benefit and as **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.

*Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.*

## **Key Points:**

This policy has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through September 14, 2017.

Assessment of efficacy for therapeutic intervention involves a determination of whether an intervention improves health outcomes. The optimal study design for this purpose is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Intermediate outcome measures, also known as surrogate outcome measures, may also be adequate if there is an established link between the intermediate outcome and true health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as noncomparability of treatment groups, placebo effect, and variable natural history of the condition. The following is a summary of the literature to date.

### Lysis

The evidence for lysis of epidural adhesions consists of single-center trials, most of them from a single U.S. pain management group. A number of systematic reviews of these trials have been identified for updates of this policy. A 2005 review article 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. Applying the U.S. Preventive Services Task Force (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 either post lumbar surgery syndrome or spinal stenosis. Complications were considered to be minimal.

In a 2008 paper, Racz et al concluded, based on the literature (randomized trials and case series) and expert opinion, that evidence was strong for short-term (three months) efficacy and moderate for long-term (>3 months) efficacy. Two systematic reviews were published in 2009, one focused on endoscopic adhesiolysis and the other on the percutaneous method. Hayek et al concluded that, based on Level II-1 or II-2 evidence (1 randomized trial and 5 observational studies), endoscopic adhesiolysis provides short- and long-term relief of pain based on the USPSTF criteria. Epter with Hayek and others concluded that there is Level-I or -II evidence (3 randomized trials and 4 observational studies) for percutaneous adhesiolysis. The latest systematic review on endoscopic adhesiolysis was published in 2013 by Helm et al. The authors included 1 randomized controlled trial (RCT) and 3 observational studies in the review and noted there is a limited amount of literature available on endoscopic adhesiolysis. Despite limitations in available evidence, using USPSTF quality of evidence criteria, the authors concluded there is 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).

The primary studies cited in the review were reviewed individually for this policy (see following sections).

#### Percutaneous Lysis of Adhesions without Spinal Endoscopy

In 2013, Gerdesmeyer et al reported on a randomized, double-blind, placebo-controlled trial on percutaneous epidural lysis of adhesions for chronic lumbar radicular pain at 4 participating treatment centers. 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 at least 4 months of unsuccessful conservative treatment. Patients in both groups 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 the control group (34 vs 20 and 42 vs 6, respectively). All neurologic deficits resolved during hospitalization. Limitations of this study 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 2009 comparative effectiveness RCTs by Manchikanti et al reported on 1-year outcomes. 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 studies, 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, all performed in the operating room, followed by transfer to the recovery room and injection of 10% sodium chloride solution and injection of betamethasone. The control group received epidurography, introduction of the catheter up to S3 or S2, repeat epidurography, injection of lidocaine in the operating room, and injection of normal saline and betamethasone in the recovery room. For the patients with failed back surgery, significant pain relief, as defined by a greater than 50% reduction in VAS, 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 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 pain reductions of 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 studies. 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 did not know which patients were participating in the studies. Several other case series have been reported, but without a control group, the independent contribution of the lysis cannot be assessed.

There are several earlier, smaller, randomized trials reported by Manchikanti and colleagues. In 2004, Manchikanti et al 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. All patients received epidural injections of local anesthetic and corticosteroids. Significant differences in pain relief, ODI, and range of motion were noted between the 2 treatment groups and the control group. A 2001 trial by Manchikanti included 45 patients who were randomized to either to receive either a one or three day course of lysis epidural adhesions. A total of 97% of the treatment group with one to three injections at least 50% pain relief at three months, which fell to 93% at 6 months, and 47% at 1 year. There was no significant improvement in the control group.

Serious adverse events from epidural lysis have been reported. In 2012, Manchikanti et al 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. 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 intravascular entry in 11.6% of cases, return of blood in 3.6%, transient nerve root irritation in 1.9%, and dural puncture in 1.8% of adhesiolysis 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 report benefits for epidural lysis of adhesions compared to placebo treatment. The interpretation of these trials is limited by differences in patients, populations and treatment protocol. 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 is also a large effect seen in the placebo group, raising questions about 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 Endoscopy

In 2003, a new category III CPT code was introduced to describe lysis of epidural lesions using endoscopic guidance. One small RCT was identified in 2003 by Manchikanti et al. Twenty-three patients with back pain of greater than 6 months in duration were randomized to receive either spinal endoscopy followed by injection of local anesthetic or corticosteroid (control group) or the above procedure with the addition of 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 the control and the intervention groups was statistically significant. There was also a significant difference between the 2 groups in the percentage of patients experiencing at least a 50% reduction in pain. Blinding appeared to be successful as 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 study reports promising results, its small size limits interpretation.

In 2011, Di Donato et al 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. 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 patients (13.7%) who had sacral pain lasting at least two weeks and 13 patients (5.5%) 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 additional articles by Manchikanti et al were identified that retrospectively examined the outcomes of patients who underwent lysis with (n=120) or without (n=60) adjunctive endoscopy. As these articles are authored by the same investigator, it is likely that they include overlapping patients. However, these studies did not include a control group, and thus scientific conclusions regarding the contribution of endoscopy are not possible.

### **Summary of Evidence**

The evidence for lysis of epidural adhesions in patients who have epidural adhesions includes randomized controlled trials (RCTs). Relevant outcomes include symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Several RCTs report benefits for epidural lysis of adhesions compared with placebo treatment. Many of these trials are from the same center. The interpretation of these trials is limited by differences in patients, populations, and treatment protocol. The treatment for lysis of adhesions varies in the use of mechanical disruption, the type of lytic medications used, and the number of injections given. There is also a large effect seen in the placebo group, raising questions about 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. 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. 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 policy.

#### American Pain Society

The American Pain Society clinical practice guideline on Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain, published in 2009, does not include a discussion or conclusion on adhesiolysis and 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 Recommendations**

Not applicable.

### **Key Words:**

Epidural Neurolysis, Hypertonic Saline Injections, Injections, Epidural, Lysis of Epidural Adhesions, Neurolysis, Adhesiolysis, Racz procedure

### **Approved by Governing Bodies:**

Not applicable

### **Benefit Application:**

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

### **Current Coding:**

CPT Codes:

<b>62263</b>	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
<b>62264</b>	; 1 day only
<b>64999</b>	Unlisted procedure, nervous system

HCPCS Codes:

<b>J7131</b>	Hypertonic saline solution, 1ml
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### **Policy History:**

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Medical Policy Group, December 2011

Medical Policy Group, March 2012

Medical Policy Group, December 2012

Medical Policy Group December 2013

Medical Policy Group, January 2015

Medical Policy Group, December 2015

Medical Policy Group, November 2017

Medical Policy Group, February 2018

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*This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.*

*This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.*