DISCLAIMER/INSTRUCTIONS FOR USE

Medical Policy provides general guidance for applying Blue Cross of Idaho benefit plans (for purposes of Medical Policy, the terms “benefit plan” and “member contract” are used interchangeably). Coverage decisions must reference the member specific benefit plan document. The terms of the member specific benefit plan document may be different than the standard benefit plan upon which this Medical Policy is based. If there is a conflict between a member specific benefit plan and the Blue Cross of Idaho’s standard benefit plan, the member specific benefit plan supersedes this Medical Policy. Any person applying this Medical Policy must identify member eligibility, the member specific benefit plan, and any related policies or guidelines prior to applying this Medical Policy. Blue Cross of Idaho Medical Policies are designed for informational purposes only and are not an authorization, explanation of benefits or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the member specific benefit plan coverage. Blue Cross of Idaho reserves the sole discretionary right to modify all its Policies and Guidelines at any time. This Medical Policy does not constitute medical advice.

POLICY

Catheter-based techniques for lysis of epidural adhesions, with or without endoscopic guidance, are considered 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.

POLICY GUIDELINES

The following CPT codes specifically identify the injection of hypertonic saline, which may be performed over the course of multiple or single days.

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; as above but limited to 1 day only.

As noted here, the protocols for lysis of epidural adhesions vary. Some institutions may perform lysis of epidural adhesions as an inpatient procedure, performed in multiple sessions over the course of several days through an indwelling catheter. In the descriptor of the CPT book, it is noted that CPT code 62263 describes the percutaneous insertion and removal of an epidural catheter and that code 62263 is not reported for each adhesiolysis treatment, but it should be reported once to describe the entire series of injection/infusion spanning 2 or more treatment days.

In 2008, CPT code 0027T (Endoscopic lysis of epidural adhesions with direct visualization using mechanical means [eg, spinal endoscopic catheter system] or solution injection (eg, normal saline)) was
deleted. Endoscopic lysis of epidural adhesions should now be coded using miscellaneous code 64999.

There is instruction following CPT code 77003 in the CPT book that states 62263 and 62264 include fluoroscopic guidance and localization.

**BENEFIT APPLICATION**

**BLUECARD/NATIONAL ACCOUNT ISSUES**
Lysis of epidural adhesions using hypertonic saline may be offered as a component of a multimodality pain management program.

**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 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 a 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.
.getenv("OMPI_PATH")
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.\(^1\) 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.\(^2\) 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.\(^3\)

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.\(^4\)

A review by Chopra et al (2005)\(^5\) 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.\(^6\) 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.\(^7\) 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.\(^8\) Of 381 patients screened, 90 patients were randomized in permuted blocks of 4 to 8 to adhesiolysis or placebo. Eligible patients had chronic lumbar 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.9,10 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.11 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.12 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. 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. 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. 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 Endoscopy**

**Randomized Controlled Trials**
One small RCT was identified by Manchikanti et al (2003). 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. 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.\textsuperscript{18,19} 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.

**SUPPLEMENTAL INFORMATION**

**PRACTICE GUIDELINES AND POSITION STATEMENTS**

**American Society of Interventional Pain Physicians**
The American Society of Interventional Pain Physicians updated its practice guidelines on the management of chronic spinal pain in 2013.\textsuperscript{20} 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 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.\textsuperscript{21} 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 RECOMMENDATIONS**
Not applicable.

**MEDICARE NATIONAL COVERAGE**
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.
ON GOING AND UNPUBLISHED CLINICAL TRIALS

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

Table 1. Summary of Key Trials

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<td>NCT01053572</td>
<td>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</td>
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<td>NCT01053273</td>
<td>Comparative Effectiveness of Percutaneous Adhesiolysis and Caudal Epidural Steroid Injections in Low Back and/or Lower Extremity Pain: A Randomized, Equivalence Trial</td>
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NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.

ESSENTIAL HEALTH BENEFITS

The Affordable Care Act (ACA) requires fully insured non-grandfathered individual and small group benefit plans to provide coverage for ten categories of Essential Health Benefits (“EHBs”), whether the benefit plans are offered through an Exchange or not. States can define EHBs for their respective state.

States vary on how they define the term small group. In Idaho, a small group employer is defined as an employer with at least two but no more than fifty eligible employees on the first day of the plan or contract year, the majority of whom are employed in Idaho. Large group employers, whether they are self-funded or fully insured, are not required to offer EHBs, but may voluntary offer them.

The Affordable Care Act requires any benefit plan offering EHBs to remove all dollar limits for EHBs.

REFERENCES


# Lysis of Epidural Adhesions

## CODES

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