



Louisiana

Lysis of Epidural Adhesions

Policy # 00037

Original Effective Date: 07/28/2003

Current Effective Date: 09/04/2018

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers catheter-based techniques for lysis of epidural adhesions, with or without endoscopic guidance, to be **investigational**.*

Note: Techniques used either alone or in combination include mechanical disruption with a catheter and/or injection of hypertonic solutions with corticosteroids, analgesics or hyaluronidase.

Background/Overview

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 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

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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.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Lysis of epidural adhesions is a surgical procedure and, as such, is not subject to regulation by the U.S. FDA.

Centers for Medicare and Medicaid Services (CMS)

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.

Rationale/Source

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 evidence review. 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 study, Racz et al 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. Two systematic reviews were published in 2009; one focused on endoscopic adhesiolysis, and the other focused on the percutaneous method. Hayek et al concluded that, based on level II-1 or II-2

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evidence (1 randomized trial, 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 was level I or II evidence (3 randomized trials, 4 observational studies) for percutaneous adhesiolysis. A 2013 systematic review on endoscopic adhesiolysis by Helm et al included an 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, 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).

The primary studies cited in these reviews were assessed individually for this evidence review (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 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 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 procedures were performed in the operating room, followed by patients being transferred to the recovery room, and

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then patients receiving 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 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 (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. 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 they 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 scores, 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 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.

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 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.

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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

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 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.

In 2011, 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 (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) were identified that examined the outcomes of patients who underwent lysis with ($n=120$) or without ($n=60$) adjunctive endoscopy. 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 scientific conclusions regarding the contribution of endoscopy are not possible.

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SUMMARY OF EVIDENCE

For individuals who have epidural adhesions who receive lysis, the evidence includes RCTs. 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 from 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.

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Policy History

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07/28/2003	Managed Care Advisory Council approval
07/14/2005	Medical Director review
07/19/2005	Medical Policy Committee review. Format revision. Rationale/Source added. Policy statement unchanged.
07/25/2005	Managed Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
08/01/2007	Medical Director review
08/15/2007	Medical Policy Committee approval. Rationale updated. No change to coverage eligibility.
08/06/2009	Medical Policy Committee approval
08/26/2009	Medical Policy Implementation Committee approval. No change to coverage eligibility.
07/01/2010	Medical Policy Committee approval
07/21/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/05/2010	Coding revision only
07/07/2011	Medical Policy Committee review
07/20/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/28/2012	Medical Policy Committee review
07/27/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/05/2013	Coding revised
06/27/2013	Medical Policy Committee review
07/17/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/10/2014	Medical Policy Committee review
07/16/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/08/2015	Medical Policy Committee review
10/21/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2016	Medical Policy Committee review
10/19/2016	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
01/01/2017	Coding update: Removing ICD-9 Diagnosis Codes
07/06/2017	Medical Policy Committee review
07/19/2017	Medical Policy Implementation Committee approval. Coding update. Coverage eligibility unchanged.

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11/07/2017 Coding update
 07/05/2018 Medical Policy Committee review
 07/11/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
 Next Scheduled Review Date: 07/2019

Coding

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Code Type	Code
CPT	62263, 62264, 62280, 62281, 62282, 64999
HCPCS	No codes
ICD-10 Diagnosis	G03.9 G96.12-G96.19 M43.00-M43.19 M48.06-M48.07 M54.5 M99.23 M99.33 M99.43 M99.53 M99.63 M99.73

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 - 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
 - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or

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3. Reference to federal regulations.

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