

No review or update is scheduled on this Medical Policy as it is unlikely that further published literature would change the policy position. If there are questions about coverage of this service, please contact Blue Cross and Blue Shield of Kansas customer service, your professional or institutional relations representative, or submit a predetermination request.

Medical Policy



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 passing 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 evidence review 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 conditions result from the manipulation of the supporting structures of the spine. Epidural fibrosis can occur in isolation, but adhesive arachnoiditis is rarely present without associated epidural fibrosis. Arachnoiditis is most frequently seen in patients who have undergone multiple surgical procedures. Epidural fibrosis and adhesive arachnoiditis are related to inflammatory reactions that result in the entrapment of nerves within dense scar tissue, increasing the susceptibility of the nerve root to compression or tension. The condition most frequently involves the nerves within the lumbar spine and cauda equina. Signs and symptoms indicate the involvement of multiple nerve roots and include low back pain, radicular pain, tenderness, sphincter disturbances, limited trunk mobility, muscular spasm or contracture, and motor-sensory and reflex changes. Typically, pain is characterized as constant and burning. In some cases, pain and disability are severe, leading to analgesic dependence and chronic invalidism. Treatment Lysis of epidural adhesions, also called the Racz procedure, has been investigated as a treatment option. The Racz procedure involves the passage of a fluoroscopically guided catheter (the Racz catheter), inserted either endoscopically or percutaneously, and the use of epidural injections of hypertonic saline in conjunction with corticosteroids and analgesics. Theoretically, the use of hypertonic saline results in mechanical disruption of the adhesions. The saline may also function to reduce edema within previously scarred and/or inflamed nerves. Finally, manipulating the catheter at the time of the injection may disrupt adhesions. Spinal endoscopy has been used to guide the lysis procedure, but the procedure is more commonly performed percutaneously using epidurography to guide catheter placement and identify nonfilling adhesions that indicate epidural scarring. Using endoscopy

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guidance, a flexible fiberoptic catheter is inserted into the sacral hiatus, providing 3-dimensional visualization to steer the catheter toward the adhesions. With the increased visualization, the catheter is more apt to precisely place the injectate in the epidural space and onto the nerve root. Various protocols for lysis have been described; in some situations, the catheter may remain in place for several days for serial treatment sessions. Endoscopic epidurolysis is also being investigated to treat degenerative chronic low back pain, including spondylolisthesis, stenosis, and hernia associated with radiculopathy. Along with mechanical adhesiolysis, hyaluronidase, ciprofloxacin, and ozone have been applied. Regulatory Status Lysis of epidural adhesions is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

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

This evidence review was created in November 1998 and has been updated regularly with searches of the PubMed database. The most recent literature update was performed through August 20, 2020. Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms. To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. Lysis The evidence for lysis of epidural adhesions consists of single-center trials, most of them from a single 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

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addressed in this evidence review is: Does the use of lysis improve the net health outcome in patients with epidural adhesions? The following PICO was used to select literature to inform this review.

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

Interventions The therapy being considered is lysis. Lysis is a surgical procedure generally administered in an inpatient hospital setting under conscious sedation using imaging guidance.

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

Outcomes The general outcomes of interest are reductions in symptoms (eg, pain severity) and medication use, improvement in functional improvement, and treatment-related adverse events (eg, neurologic deficits). Postsurgical follow-up can range from 6 to 8 weeks.

Review of Evidence

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 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 U.S. Preventive Services Task Force criteria.
- 2, Epter et al (2009) with Hayek et al (2009) and others concluded that there was level I or II evidence (3 randomized trials, 4 observational studies) for percutaneous adhesiolysis.
- 3,2, 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 U.S. Preventive Services Task Force 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 the following sections).

Percutaneous Lysis of Adhesions Without Spinal Endoscopy

Review of Evidence

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 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 an 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

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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; p50% reduction in VAS score) was achieved by 73% of patients in the lysis group compared with 12% in the control group (p

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"> ▪ Removed HCPCS code: J7130 ▪ Added HCPCS code: J7131 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"> ▪ Removed HCPCS code: J7131 ▪ Added HCPCS code: J7130

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	<ul style="list-style-type: none"> ▪ Removed reference to ICD-9 codes 349.0-349.9
	Updated Rationale section.
	Updated Reference section.
02-16-2015	Updated Description section.
	Updated Rationale section.
	In Coding section: <ul style="list-style-type: none"> ▪ Removed HCPCS code: J7130
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.
02-25-2021	Updated Description section.
	Updated Rationale section.
	Updated References section.
06-03-2021	Archived

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