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Medical Policy Manual Surgery, Policy No. 94

Lysis of Epidural Adhesions

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IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Lysis of epidural adhesions involves passage of a catheter endoscopically or percutaneously under fluoroscopic guidance into the epidural space to break up adhesions. Various agents, such as anesthetics, corticosteroids, hyaluronidase, and hypertonic saline, may be injected to reduce pain and inflammation.

MEDICAL POLICY CRITERIA

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

NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.

CROSS REFERENCES

None

BACKGROUND

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 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, 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 known as the Racz procedure), using fluoroscopic guidance, with epidural injections of hypertonic saline in conjunction with steroids 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, adhesions may be disrupted by manipulating the catheter at the time of the injection. Spinal endoscopy has been used to guide the lysis procedure. Prior to 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.

EVIDENCE SUMMARY

Evidence from large, well-designed randomized controlled trials (RCTs) with adequate duration of follow-up are necessary in order to demonstrate the safety and effectiveness of lysis of epidural adhesions.

LYSIS OF EPIDURAL ADHESIONS WITH OR WITHOUT SPINAL ENDOSCOPY

Systematic Reviews

A systematic review by Brito-Garcia (2019) assessed the efficacy, effectiveness, safety, and cost-effectiveness of epidural adhesiolysis for the treatment of failed back surgery syndrome.[1] Ten articles were included in the review, three of which reported on two RCTs (described below), and seven observational studies. No studies were found that evaluated efficacy or cost-effectiveness. While the included studies suggested that adhesiolysis may be effective for treating back pain and disability, the authors noted that the published RCTs had serious limitations in their methodology and substantial risk of bias.

Cho (2017) published a systematic review that evaluated several treatment options for failed back surgery syndrome (FBSS).[2] Five studies were evaluated specifically for epidural adhesiolysis (two RCTs, two systematic reviews, and one observational study). The authors concluded epidural adhesiolysis can be effective in treating chronic pain from FBSS based on the two excellent quality RCTs. Although, it's important to note that none of the studies evaluated long-term outcomes, the quality of the systematic reviews was noted to be I, II-1 or

fair according to the US Preventive Services Task Force (USPSTF) criteria and more research is needed to support the evidence.

Randomized Control Trials

No RCTS were identified that were published since the above systematic review.

PERCUTANEOUS LYSIS OF ADHESIONS WITHOUT SPINAL ENDOSCOPY

Randomized Controlled Trials (RCTs)

Gerdesmeyer (2013) randomized 381 patients with chronic radicular pain lasting longer than four months which failed to respond with conservative therapy using a prospective study design.[3] Patients were randomly assigned to receive either percutaneous neurolysis or placebo with concealed allocation in permuted blocks of four to eight, stratified by treatment center. The primary outcome measure was the differences in percent change of Oswestry Disability Index (ODI) scores three months after intervention. However, limitations of the study included single treatment components could not be specified because there was no imaging examination after treatment.

A 10-year follow-up to the Gerdesmeyer study described above was published to determine if the difference in outcomes remained between the treatment and control groups.[4] Results from the follow-up showed that ODI in the lysis group improved from 55.3 ± 11.6 to 9.6 ± 9.3 after one year and to 11.7 ± 14.2 after 10 years. The placebo group also improved from 55.4 ± 11.5 to 30.7 ± 14.2 after one year and to 24.8 ± 12.0 after 10 years. Additionally, VAS improved from 6.7 ± 1.1 to 1.2 ± 1.1 after one year and to 1.5 ± 1.4 after 10 years in the lysis group and from 6.7 ± 1.1 to 2.8 ± 1.5 after one year and to 2.9 ± 1.3 after 10 years after placebo intervention. The authors concluded that the statistical difference for ODI and VAS remained significant for up to 10 years between the treatment groups. No treatment-related severe adverse effects occurred within the 10 years, but minor transient neurological effects were seen directly after the intervention. This follow-up study is limited based on no-follow up imaging evaluation and uncontrolled for the large variety of noninvasive treatments done during the follow-up period.

Two comparative effectiveness RCTs by Manchikanti (2009)[5, 6] report one-year outcomes. Patients in one trial had failed back surgery syndrome (planned enrollment, 200 patients), and patients in the other had chronic low back pain secondary to spinal stenosis (planned enrollment, 120 patients). The reason for reporting preliminary results is not given, but the authors note that in the larger study of patients with failed back surgery, having 60 patients in each group was determined to be adequate, and there are no controlled trials of patients receiving lysis of epidural adhesions for back pain related to spinal stenosis reported in the literature. 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. After all procedures were performed, patients received an 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, and 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 two-year follow-up report on this study, Manchikanti (2012) reported 82% of patients receiving adhesiolysis had significant improvement in functional status and relief of pain of at least 50% compared to only 5% improvement in the epidural corticosteroid injection group.[7] If patients had improved functioning and pain reductions of at least 50% after at least three 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 two-year period.

A number of limitations are apparent in the studies. Losses to follow-up in the control groups were large in both studies (10 of 60 at six months and 43 of 60 at 12 months in the failed back surgery study, and 10 of 25 at six months and 18 of 25 at 12 months in the spinal stenosis study). 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.

Manchikanti (2004) published the results of a trial that randomized 75 patients to one of three groups, either a control group consisting of catheterization without adhesiolysis, or to adhesiolysis with or without additional hypertonic saline.[8] All patients received epidural injections of local anesthetic and steroids. Significant differences in pain relief, ODI scores, and range of motion were noted between the two treatment groups and the control group. In another trial, Manchikanti (2001) randomized 45 patients to a one- or a three-day course of lysis of epidural adhesions.[9] A total of 97% of the treatment group with one to three injections reported at least 50% pain relief at three months, which fell to 93% at six months, and to 47% at one year. There were no significant improvements in the control group.

Other RCTs of lysis of epidural adhesions have been published; however these trials have significant methodological limitations, such as small sample size and/or short duration of follow-up.[10-12]

Nonrandomized Studies

Serious adverse events from epidural lysis have been reported.[13] Manchikanti (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.[14] 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.

PERCUTANEOUS LYSIS OF ADHESIONS WITH SPINAL ENDOSCOPY

Systematic Reviews

Helm (2012) evaluated the effectiveness of percutaneous adhesiolysis in the treatment of refractory low back and leg pain due to post lumbar surgery syndrome or spinal stenosis. The

severity of risks and adverse advents associated with percutaneous adhesiolysis were also evaluated.[15] Authors applied the U.S. Preventive Services Task Force (USPSTF) criteria to the 15 studies identified and selected for review. Authors 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.

In an update of the review described above, Helm (2013) evaluated endoscopic adhesiolysis.[16] The authors included one RCT and three 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).

Randomized Controlled Trials (RCTs)

Two RCTs by Manchikanti were included in the systematic reviews previously described. One 2003 double-blinded trial randomized 23 patients with back pain of greater than six months' duration to receive either spinal endoscopy followed by injection of local anesthetic or steroid (control group) or the above procedure with the addition of lysis of adhesions with normal saline and mechanical disruption with the fiberoptic endoscope.[17] 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 the VAS scores and Oswestry Disability scale at six months. In the control group the mean VAS score dropped from 8.7 at baseline to 7.6 at six months, while the scores in the intervention group dropped from 9.2 at baseline to 5.7 at six months. The difference between the control and intervention group was statistically significant. There was also a significant difference between the two groups in the percentage of patients experiencing at least a 50% reduction in pain. Blinding appeared to be successful as six of the 16 patients in the control group believed that they were in the intervention group, and eight of 23 patients in the intervention group believed that they were in the control group. While this study reports promising results, its small size limits reliability of the findings.

In the second study, Manchikanti (2005) reported results of a randomized trial of endoscopic adhesiolysis compared to caudal epidural steroid injection.[18] Again, the independent contribution of the adhesiolysis cannot be assessed as targeted injections of both local anesthetic and steroids were given to the intervention group. In addition, a true comparison between treatment and control groups cannot be made as the control group received local anesthetic and steroid injections at S3, whereas the intervention group received targeted injections following adhesiolysis at the level of suspected pathology (L4, L5, and S1). Other methodologic issues limiting reliability interpretation of the study outcomes include the introduction of bias as a result of 2:3 randomization (patients entered the study believing they had a higher chance of being included in the treatment group) and the unblinding of some patients at three months, although an intent-to-treat analysis was performed.

Nonrandomized Studies

Nonrandomized studies have evaluated lumbar endoscopic adhesiolysis following discectomy, but the studies have significant limitations, including small sample size and lack of controls.[19] Case series reporting on lysis of epidural adhesions have been published as well; however, evidence from case series is considered unreliable due to methodological limitations, including

but not limited to lack of an adequate comparison group, without which it is not possible to account for the many types of bias that can affect study outcomes.[20-23]

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 randomized controlled trials 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 GUIDELINE SUMMARY

AMERICAN SOCIETY OF INTERVENTIONAL PAIN PHYSICIANS (ASIPP)

The ASIPP updated their practice guidelines on the management of chronic spinal pain in 2013.[24] 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.” It further states that “due to limited evidence and rate use of spinal epidural endoscopic adhesiolysis, it is not discussed.” The 2009 ASIPP guideline states that, “evidence is moderate in managing low back and lower extremity pain secondary to disc herniation producing radiculopathy.[25] The evidence is limited in managing back and/or lower extremity pain secondary to spinal stenosis.” The studies supporting the guideline recommendations have been reviewed in this policy.

AMERICAN PAIN SOCIETY (APS)

The APS 2009 evidence-based clinical practice guideline on interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain, does not include a specific discussion or conclusion on adhesiolysis; however, the guideline states that, “for other interventions or specific clinical circumstances, the panel found insufficient evidence from randomized controlled trials to reliably judge benefits or harms.”[26]

SUMMARY

There is not enough research to show that catheter-based techniques for lysis of epidural adhesions, with or without endoscopic guidance improves health outcomes. No clinical guidelines based on research recommend these techniques. Therefore, lysis of epidural adhesions, with or without endoscopic guidance, is considered investigational.

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CODES

Codes	Number	Description
CPT	62263	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
	62264	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;1 day
	64999	Unlisted procedure, nervous system
HCPCS	None	

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