Lysis of Epidural Adhesions

Effective: November 1, 2018

Next Review: September 2019
Last Review: October 2018

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

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 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, 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

Cho (2017) published a systematic review (SR) that evaluated several treatment options for failed back surgery syndrome (FBSS).[1] Five studies were evaluated specifically for epidural adhesiolysis (two RCTs, two SRs, 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 outcomes long term, the quality of the SRs 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 SR.

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.[2] Patients were randomly assigned to receive either percutaneous neurolysis or placebo with concealed allocation in permuted blocks of 4 to 8, 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.

Two papers by Manchikanti (2009)[3,4] report one-year outcomes of two comparative effectiveness, RCTs currently underway. 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, 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, and injection of lidocaine in the operating room and injection of normal saline and betamethasone in the recovery room. Besides the preliminary nature of the reports, a number of limitations are apparent in the studies. Efficacy of the comparator, epidural corticosteroid injection, has not been clearly demonstrated.[5] The injection site in the control group may have had some impact on outcomes. 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 6 months and 18 of 25 at 12 months in the spinal stenosis study). There were no drop-outs 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. Once unblinded, patients were considered withdrawn from the study. If the patient chose not to be unblinded, the prior treatment was repeated as assigned. Physicians performing procedures could not be blinded to treatment group but did not know which patients were participating in the studies. It was not reported if patients were asked which treatment they thought they received.

In the two-year follow-up report on the study with 120 patients treated for chronic low back pain, 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.[6] 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.

Manchikanti (2004) published the results of a trial that randomized 75 patients to one of three groups:[7]

1. Catheterization without adhesiolysis
2. Adhesiolysis with additional hypertonic saline
3. Adhesiolysis without additional hypertonic saline

All patients received epidural injections of local anesthetic and steroids. Patient selection criteria included a history of chronic low back pain of at least two years that had failed conservative treatment, including epidural steroid injections. Outcomes were assessed at three, six and 12 months based on VAS pain scale, Oswestry Disability Index, work status, opioid intake, range of motion, and psychological exam. Unblinding was allowed at three months based on treatment response, followed by crossover to another treatment group. It is not clear from the published article how this assessment was made. In the control group of 25 patients, six patients were unblinded at three months, 12 at six months, and six at 12 months. Once patients were unblinded, they were considered withdrawn, and no subsequent data was collected. The results of their last assessment were carried forward to the next assessment. For example, if a patient was unblinded at three months, the same outcomes were reported at six and 12 months. Therefore, this discussion focuses on the three-month outcomes. Significant differences in pain relief, Oswestry Disability Index and range of motion were noted between the two treatment groups and the control group. For example, the mean VAS score was not significantly improved in the control group, dropping from 8.9 to 7.7, while in the treatment groups the VAS dropped from 8.8 to 4.6. A total of 40% of the control group had no response with the first treatment, compared to only 16% in the adhesiolysis group. At three months, no patient in the control group reported significant relief, defined as at least 50% relief, while at least 64% of patients in the treatment group reported significant relief. Small sample size limits reliability of the study findings. The dramatic effect reported in this study needs to be confirmed in a larger multi-institutional study.

Other reported trials also have significant methodologic limitations. One trial included 45 patients who were randomized to receive either a one- or three-day course of lysis of epidural adhesions, although details of the randomization and treatment protocols are not provided, and it is not clear what, if any, randomization took place.[8] The trial also included a conservatively treated control group of 15 patients who either refused the treatment option, or whose insurance refused to pay. Although the study did not provide details on how pain relief was evaluated, describing only a verbal 10-point scale, the study concluded that a total of 97% of the treatment group reported at least 50% pain relief with 1 to 3 injections at three months, which fell to 93% at 6 months, and 47% at one year. There was no significant improvement in the control group. However, the lack of a placebo control and the obvious bias of the control group limit the interpretation of these findings. One study compared the use of 0.9% saline solution versus 10% saline solution but did not control other aspects of the pain management program.[9]

One randomized single-blinded trial compared epidural lysis with physiotherapy in 99 patients with chronic low back pain.[10] Inclusions criteria were radicular pain with a corresponding nerve root compressing substrate, and included patients with disc protrusion and herniation as well as epidural fibrosis. The authors did not present the results according to these separate indicators. Therefore, for purposes of this policy, the study results cannot be evaluated.

Other RCTs of lysis of epidural adhesions have been published; however these trials as well have significant methodological limitations, such as small sample size and/or short duration of follow-up.[11]

Nonrandomized Studies

Serious adverse events from epidural lysis have been reported.[12] 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.[13] 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

Several small RCTs report benefits for epidural lysis of adhesions compared with placebo treatment. The interpretation of these trials is limited by differences in patients 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 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 are needed to in determine whether specific treatment protocols have beneficial effects in specific patient populations.

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.[14] 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 92013) conducted a SR on endoscopic adhesiolysis.[15] 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 SRs previously described. One 2003 double-blind 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.[16] 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.[17] 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.[18] 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.[19-22]

Section Summary

Two SRs describe the level of evidence as fair for the benefits of spinal endoscopic adhesiolysis in reducing chronic low back and/or leg pain. The available RCTs are limited by small sample size, lack of a true control group, introduction of bias due to unblinding of subjects, and the use of 2:3 randomization. Due to the methodological limitations bias may have been introduced into the study designs, therefore the interpretation of the results are limited and may not be reliable.

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.[23] 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.[24] 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."[25]

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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