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Medical Benefit		Effective Date: 04/01/13	Next Review Date: 01/21
Preauthorization	No	Review Dates: 03/07, 05/08, 05/09, 05/10, 05/11, 01/12, 01/13, 01/14, 01/15, 01/16, 01/17, 01/18, 01/19, 01/20	

This protocol considers this test or procedure investigational. If the physician feels this service is medically necessary, preauthorization is recommended.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: <ul style="list-style-type: none"> With epidural adhesions 	Interventions of interest are: <ul style="list-style-type: none"> Lysis 	Comparators of interest are: <ul style="list-style-type: none"> Medical management 	Relevant outcomes include: <ul style="list-style-type: none"> 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.

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.

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.

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 three-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.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary

Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Helm S, Hayek SM, Colson J, et al. Spinal endoscopic adhesiolysis in post lumbar surgery syndrome: an update of assessment of the evidence. *Pain Physician*. Apr 2013;16(2 Suppl):SE125-150. PMID 23615889
2. Hayek SM, Helm S, Benyamin RM, et al. Effectiveness of spinal endoscopic adhesiolysis in post lumbar surgery syndrome: a systematic review. *Pain Physician*. Mar-Apr 2009;12(2):419-435. PMID 19305488
3. Epter RS, Helm S, 2nd, Hayek SM, et al. Systematic review of percutaneous adhesiolysis and management of chronic low back pain in post lumbar surgery syndrome. *Pain Physician*. Mar-Apr 2009;12(2):361-378. PMID 19305485
4. Racz GB, Heavner JE, Trescot A. Percutaneous lysis of epidural adhesions--evidence for safety and efficacy. *Pain Pract*. Jul-Aug 2008;8(4):277-286. PMID 18503627
5. Chopra P, Smith HS, Deer TR, et al. Role of adhesiolysis in the management of chronic spinal pain: a systematic review of effectiveness and complications. *Pain Physician*. Jan 2005;8(1):87-100. PMID 16850047
6. Trescot AM, Chopra P, Abdi S, et al. Systematic review of effectiveness and complications of adhesiolysis in the management of chronic spinal pain: an update. *Pain Physician*. Jan 2007;10(1):129-146. PMID 17256027
7. Helm S, Benyamin RM, Chopra P, et al. Percutaneous adhesiolysis in the management of chronic low back pain in post lumbar surgery syndrome and spinal stenosis: a systematic review. *Pain Physician*. Jul-Aug 2012;15(4):E435-462. PMID 22828693
8. Gerdesmeyer L, Wagenpfeil S, Birkenmaier C, et al. Percutaneous epidural lysis of adhesions in chronic lumbar radicular pain: a randomized, double-blind, placebo-controlled trial. *Pain Physician*. May-Jun 2013;16(3):185-196. PMID 23703406
9. Manchikanti L, Cash KA, McManus CD, et al. The preliminary results of a comparative effectiveness evaluation of adhesiolysis and caudal epidural injections in managing chronic low back pain secondary to spinal stenosis: a randomized, equivalence controlled trial. *Pain Physician*. Nov-Dec 2009;12(6):E341-354. PMID 19935991
10. Manchikanti L, Singh V, Cash KA, et al. A comparative effectiveness evaluation of percutaneous adhesiolysis and epidural steroid injections in managing lumbar post surgery syndrome: a randomized, equivalence controlled trial. *Pain Physician*. Nov-Dec 2009;12(6):E355-368. PMID 19935992
11. Manchikanti L, Singh V, Cash KA, et al. Assessment of effectiveness of percutaneous adhesiolysis and caudal epidural injections in managing post lumbar surgery syndrome: 2-year follow-up of a randomized, controlled trial. *J Pain Res*. Jan 2012;5:597-608. PMID 23293536
12. Manchikanti L, Rivera JJ, Pampati V, et al. One day lumbar epidural adhesiolysis and hypertonic saline neurolysis in treatment of chronic low back pain: a randomized, double-blind trial. *Pain Physician*. Apr 2004;7(2):177-186. PMID 16868590
13. Manchikanti L, Pampati V, Fellows B, et al. Role of one day epidural adhesiolysis in management of chronic low back pain: a randomized clinical trial. *Pain Physician*. Apr 2001;4(2):153-166. PMID 16902688

14. Wagner KJ, Sprenger T, Pecho C, et al. [Risks and complications of epidural neurolysis -- a review with case report] [German]. *Anesthesiol Intensivmed Notfallmed Schmerzther.* Apr 2006;41(4):213-222. PMID 16636945
15. Manchikanti L, Malla Y, Wargo BW, et al. A prospective evaluation of complications of 10,000 fluoroscopically directed epidural injections. *Pain Physician.* Mar-Apr 2012;15(2):131-140. PMID 22430650
16. Manchikanti L, Rivera JJ, Pampati V, et al. Spinal endoscopic adhesiolysis in the management of chronic low back pain: a preliminary report of a randomized, double-blind trial. *Pain Physician.* Jul 2003;6(3):259-267. PMID 16880869
17. Donato AD, Fontana C, Pinto R, et al. The effectiveness of endoscopic epidurolysis in treatment of degenerative chronic low back pain: a prospective analysis and follow-up at 48 months. *Acta Neurochir Suppl.* Nov 2011;108:67-73. PMID 21107940
18. Manchikanti L, Pampati V, Bakhit CE, et al. Non-endoscopic and endoscopic adhesiolysis in post-lumbar laminectomy syndrome: a one-year outcome study and cost effectiveness analysis. *Pain Physician.* Oct 1999; 2(3):52-58. PMID 16906216
19. Manchikanti L, Pakanati RR, Pampati V. The value and safety of epidural endoscopic adhesiolysis. *Am J Anesthesiol.* 2000;27(5):275-279. PMID
20. Manchikanti L, Abdi S, Atluri S, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician.* Apr 2013; 16(2 Suppl):S49-283. PMID 23615883
21. Chou R, Loeser JD, Owens DK, et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine (Phila Pa 1976).* May 1 2009;34(10):1066-1077. PMID 19363457