

## FEP 8.01.18 Lysis of Epidural Adhesions

**Effective Date:** April 15, 2018

**Related Policies:** None

### Lysis of Epidural Adhesions

#### 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. Lysis of epidural adhesions, also called the Racz procedure, has been investigated as a treatment option for epidural fibrosis with or without adhesive arachnoiditis. 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.

#### FDA 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. The Racz catheter received FDA approval via the 510k process.

#### POLICY STATEMENT

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.

#### BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

#### RATIONALE

##### 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 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

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beneficial effects in specific patient populations. The evidence is insufficient to determine the effects of the technology on health outcomes.

### SUPPLEMENTAL INFORMATION

#### Practice Guidelines and Position Statements

##### American Society of Interventional Pain Physicians

The American Society of Interventional Pain Physicians updated its practice guidelines on the management of chronic spinal pain in 2013.<sup>20</sup> The guidelines stated 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.” Percutaneous adhesiolysis was recommended “after failure of conservative management of physical therapy, chiropractic, drug therapy, structured exercise program, and fluoroscopically directed epidural injections.” The guidelines also indicated that spinal epidural endoscopic adhesiolysis was not discussed because there is limited evidence, moreover the procedure is rarely used. The studies cited in the guidelines were evaluated for this evidence review.

##### American Pain Society

The American Pain Society’s 2009 clinical practice guidelines on interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain did not include a discussion or conclusion on adhesiolysis.<sup>21</sup> The guidelines stated that “for other interventions or specific clinical circumstances, the panel found insufficient evidence from randomized controlled trials to reliably judge benefits or harms.”

#### U.S. Preventive Services Task Force Recommendations

Not applicable.

#### Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

### REFERENCES

1. 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
2. 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
3. Helm li 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
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. 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
6. 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
7. 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
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

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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

### POLICY HISTORY

Date	Action	Description
December 2011	New Policy	
June 2012	Update Policy	Policy statement changed to read not medically necessary. Reference number 17 added. Remaining references renumbered.
March 2013	Update Policy	Policy updated with literature review; references 3 and 11 added, others reordered, policy statement unchanged.
March 2014	Update Policy	Policy updated with literature review, references 7, 8, 11, and 23 were added. The policy statement is unchanged.
March 2015	Update Policy	Policy updated with literature review through November 17, 2014. No references were added, policy statement was unchanged.
June 2016	Update Policy	Policy updated with literature review through November 11, 2015; no references added. Policy statement unchanged.
March 2018	Update Policy	Policy updated with literature review through September 14, 2017; no references were added. Policy statement unchanged except not medically necessary" corrected to "investigational".

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