



Clinical Review Criteria Epidural Lysis of Adhesions for Chronic Low-Back Pain

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Criteria

For Medicare Members

Source	Policy
CMS Coverage Manuals	None
National Coverage Determinations (NCD)	None
Local Coverage Determinations (LCD)	None
Local Coverage Article	None
Kaiser Permanente Medical Policy	Due to the absence of an active NCD, LCD, or other coverage guidance, Kaiser Permanente has chosen to use their own Clinical Review Criteria, " Epidural Lysis of Adhesions for Chronic Low-Back Pain " for medical necessity determinations. Refer to the Non-Medicare criteria below.

For Non-Medicare Members

There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies and/or provides better long-term outcomes than current standard services/therapies.

If requesting review for this service, please send the following documentation:

- Last 6 months of clinical notes from requesting provider &/or specialist

The following information was used in the development of this document and is provided as background only. It is provided for historical purposes and does not necessarily reflect the most current published literature. When significant new articles are published that impact treatment option, Kaiser Permanente will review as needed. This information is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background

Estimates for the prevalence of back pain in a lifetime range from 54% to 80%. Chronic persistent back pain is seen in up to 60% of patients five years after the initial episode. Back pain is associated with substantial economic and social costs (Boswell et al., 2005).

Epidural lysis of adhesions (also known as epidural adhesiolysis) is a procedure developed by Dr. Gabor Racz in 1989 to treat chronic low back pain in patients who have failed to respond to conservative treatments. The goals of the procedure are to break down fibrous adhesions in the epidural space and apply medication (i.e. local anesthetics and corticosteroids). Fibrous epidural lesions can develop after surgical laminectomy, or can occur secondary to annular tear, hematoma or infection. The adhesions prevent free movement of structures in the intervertebral foramen and the bony vertebral canal and prevent direct application of medications to structures believed to be the source of pain. The role of fibrous epidural adhesions in causing chronic spinal pain, however, remains controversial (Belozer & Wang, 2004; Manchikanti et al., 2004).

The basic procedure for epidural lysis of adhesions is as follows: A 16-gauge RK needle enters the epidural space and contrast material is injected. Next, an epidurogram is performed to visualize spread of contrast medium

and identify filling defects. If the filling defect corresponds to the area of pain, a specially designed spring-guided reinforced catheter (Racz catheter) is threaded into the filling defect. Lysis of adhesions is carried out by intermittent injections of normal or hypertonic saline through the catheter. After adhesiolysis, local anesthetic and corticosteroids are injected. The original procedure, as described by Racz, requires the catheter to stay in place for 3-days, with additional injections of local anesthetic and steroid occurring on days 2 and 3. The procedure was modified to a 1-day protocol by Manchikanti and colleagues (Heavner et al., 1999).

Patients often undergo multiple adhesiolysis treatments. The American Society of Interventional Pain Physicians (ASIPP) suggests that with a 3-day protocol, patients should be limited to 2 interventions per year and with a 1-day protocol, patients should be limited to 4 interventions per year. Spinal endoscopic adhesiolysis procedures should be limited to a maximum of 2 per year, provided that the patient experienced at least a 50% reduction in pain for at least 2 months (Boswell et al., 2005).

Epidural adhesiolysis can be conducted with a spinal endoscope (called a myeloscope). This allows a 3-dimensional view of the contents of the epidural space. Proponents believe that spinal endoscopy improves the ability to perform appropriate adhesiolysis and provide targeted administration of medications (Belozer & Wang, 2004).

Possible side effects of epidural lysis of adhesions include dural puncture, spinal cord compression, infection and administration of high volumes of fluids which would potentially result in excessive epidural hydrostatic pressures (Boswell et al., 2005). In addition, the FDA has received multiple reports of catheter shearing or unraveling, as recently as April 2005. In most of these cases, sheared catheter pieces were left inside the patient (FDA website).

The Racz epidural catheter received premarket approval from the FDA in 1996.

Medical Technology Assessment Committee (MTAC)

Epidural Lysis of Adhesions

04/03/2006: MTAC REVIEW

Evidence Conclusion: One RCT evaluated the 3-day procedure for epidural lysis of adhesions. Conclusions cannot be drawn about effectiveness of this treatment from the study because there was no control group that did not receive the treatment. The study compared three alternate ways of performing the procedure. In addition, conclusions cannot be drawn about the relative effectiveness of different ways of performing the procedure since a between-group statistical analysis was not reported. Study validity was limited by a high drop-out rate and no intention to treat analysis, and lack of details about randomization and blinding procedures. Two RCTs evaluated the 1-day procedure for epidural lysis of adhesions. Both were conducted by Manchikanti and colleagues, the group that developed the shortened procedure. One of these was on percutaneous adhesiolysis (Manchikanti et al., 2004) and the other was on spinal endoscopic adhesiolysis (Manchikanti et al., 2005). The studies had similar methodology, and similar findings. Manchikanti et al., 2004 found significantly lower pain in each of two groups receiving epidural adhesiolysis (one received normal saline and the other, hypertonic saline) compared to a no treatment control group at 3, 6 and 12 months. Manchikanti et al., 2005 found significantly lower pain in a group receiving spinal endoscopic adhesiolysis compared to a no treatment control group at 3, 6 and 12 months. In both studies, the authors reported multiple outcomes without specifying primary outcomes or adjusting their p-value for multiple comparisons. Actual p-values were low enough that most of the differences would still have been statistically significant if the p-value had been adjusted. The clinical significance of outcomes using the VAS scale is not clear, but a substantially higher proportion of patients experienced ³50% pain reliefs. A limitation of the two studies was that patients could choose to be unblinded at 3 months, which could bias responses at 6 and 12 months. 25% of patients in the control group in the Manchikanti et al., 2004 study and 33% of all patients in the Manchikanti et al., 2005 study chose to be unblinded at 3 months.

Articles: Three randomized controlled trials were identified and critically appraised. One was on the original 3-day procedure and two were on the 1-day procedure. In addition, one non-randomized controlled trial and several case series were identified. The non-randomized controlled trial was not evaluated further because there were two later RCTs by the same research group on the 1-day procedure. The RCTs were: Heavner JE, Racz GB, Raj P. Percutaneous epidural neuroplasty: Prospective evaluation of 0.9% NaCl versus 10% NaCl with or without hyaluronidase. *Reg Anesthesia Pain Med* 1999; 24: 202-207. See [Evidence Table](#). 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* 2004; 7: 177-186. See [Evidence Table](#). Manchikanti L, Boswell MV, Rivera JJ et al. A randomized, controlled trial of spinal endoscopic adhesiolysis in chronic refractory low back and lower extremity pain. *BMC Anesthesiology* 2005; 5:10. See [Evidence Table](#).

The use of Epidural Lysis of Adhesions in the evaluation of chronic low-back pain does not meet the *Kaiser Permanente Medical Technology Assessment Criteria*.

Applicable Codes

Considered Not Medically Necessary:

CPT® or HCPC Codes	Description
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

***Note:** Codes may not be all-inclusive. Deleted codes and codes not in effect at the time of service may not be covered.

**To verify authorization requirements for a specific code by plan type, please use the [Pre-authorization Code Check](#).

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04/27/2006	04/20/2006 ^{MDCRPC} , 03/19/2007 ^{MDCRPC} , 12/17/2007 ^{MDCRPC} , 09/08/2008 ^{MDCRPC} , 07/13/2009 ^{MDCRPC} , 06/01/2010 ^{MDCRPC} , 04/05/2011 ^{MDCRPC} , 02/07/2012 ^{MDCRPC} , 12/04/2012 ^{MDCRPC} , 10/01/2013 ^{MPC} , 08/05/2014 ^{MPC} , 06/02/2015 ^{MPC} , 04/05/2016 ^{MPC} , 02/07/2017 ^{MPC} , 12/05/2017 ^{MPC} , 10/02/2018 ^{MPC} , 10/01/2019 ^{MPC} , 10/06/2020 ^{MPC} , 10/05/2021 ^{MPC} , 10/04/2022 ^{MPC} , 10/03/2023 ^{MPC}	09/08/2015

^{MDCRPC} Medical Director Clinical Review and Policy Committee
^{MPC} Medical Policy Committee

Revision History	Description
09/08/2015	Revised LCD L34886 and L35008 Non-Covered Services.