

MEDICAL POLICY		Back: Lysis of Epidural Adhesions	
Effective Date: 7/1/2020		Section: SUR	Policy No.: 122
 <div style="text-align: right;">7/1/2020</div>		Technology Assessment Committee Approved Date: 3/13; 3/14; 2/15	
		Medical Policy Committee Approved Date: 2/16; 7/17; 12/18; 1/19; 2/2020; 8/2020	
Medical Officer	Date		

See Policy CPT CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

Percutaneous or endoscopic lysis of epidural adhesions (i.e., Racz Procedure, adhesiolysis, epiduroscopy, epidurolysis, or epidural neuroplasty) for the treatment of back pain is considered **not medically necessary and is not covered.**

CPT CODES

All Lines of Business	
Not Covered	
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

MEDICAL POLICY	Back: Lysis of Epidural Adhesions
-----------------------	--

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
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be denied as not covered .	
64999	Unlisted procedure, nervous system

DESCRIPTION

Epidural Adhesiolysis for Back Pain

Epidural adhesiolysis (the removal of spinal adhesions) is a surgical procedure proposed for the treatment of chronic back pain.¹ Spinal adhesions, also known as epidural fibrosis, are commonly due to spinal surgery which has caused scar tissue build-up in the epidural space (the region between the spinal cord and vertebrae). This excess tissue can obstruct the spinal nerves and cause significant back pain. Spinal adhesions can also be caused by aging and subsequent spinal degeneration, inflammation, or infection. To remove these spinal adhesions, an epidural needle is placed and an epidurogram (injecting contrast dye to assess the structure of the epidural space) is conducted to localize the source of the fibrosis. Once the defect is identified, a catheter is placed and local anesthetic with saline is injected in order to expand and decompress the epidural space. The catheter is then maneuvered in a way which lyses the spinal adhesions. In order to provide a visual aide and guidance for the procedure, a fiber-optic endoscope is sometimes used when removing the spinal adhesions (i.e., epiduroscopy).

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding lysis of epidural adhesions for the treatment of back pain. Below is a summary of the available evidence identified through January 2020.

Systematic Reviews

- In 2018 (annually reviewed October 2019), Hayes conducted a systematic review to evaluate percutaneous epidural adhesiolysis (PA) for the treatment of chronic lower back pain (CLBP).¹ The review comprised 7 publications deriving from 6 randomized controlled trials (RCTs). The sample sizes ranged from 50 to 120 patients presenting with varying types of CLBP, who had failed to respond to previous treatments. Follow-up ranged from 3 months to 2 years. Primary outcomes measured were pain, functionality, opioid or analgesic use, and complications.

One RCT compared PA with physical therapy for the treatment of CLBP with sciatica and reported statistically significant improvements in back pain, overall function, and leg pain compared to the physical therapy-only group at the 12-month follow-up. Another RCT compared PA with epidural injections and reported statistically significant improvements in mean pain and function scores at 12 months, and clinically significant improvement compared to the epidural-only group at each follow-

up period (3-, 6- and 12-months). Two RCTs compared PA with epidural injection in patients with failed back surgery syndrome. The first showed statistically significant reductions in mean pain and function scores compared to baseline at 12 months. A 2-year follow up study of the same patient population found that mean pain and function scores were significantly improved in the PA group compared to the epidural injection group. All studies included in the review reported a low incidence of complications.

Hayes rated the overall quality of evidence as “low”, with four of the six included studies rated as “good quality” and two as “poor quality.” Limitations included incomplete blinding of assessors, incomplete descriptions of methods, and high attrition among patient populations. Hayes gave a “C” rating (potential but unproven benefit) for the use of PA given low-quality evidence indicating short- and intermediate-term efficacy among patients for whom more conservative treatments have failed. Hayes called for additional well-designed studies with longer follow-up periods to determine if epidural adhesions are the actual source of patients’ CLBP.

- In 2012, Helm and colleagues conducted a systematic review to evaluate percutaneous adhesiolysis in the management of chronic low back pain in post lumbar surgery syndrome and spinal stenosis.² Independent reviewers systematically identified eligible studies, assessed quality, and extracted data. Study authors were also contacted, if necessary, for additional information or data. The outcomes of interest were pain relief for at least 6 months, functional improvement, change in psychological status, return to work, continued opioid use, other drugs or other interventions, and complications.

The authors identified 7 publications eligible for inclusion, of which 5 were randomized controlled trials and 2 were observational, nonrandomized studies. Due to heterogeneity between studies, meta-analysis was not possible. The results of these studies indicated adhesiolysis is effective in the treatment of chronic low back and leg pain due to post lumbar surgery syndrome and/or spinal stenosis; however, the level of evidence was determined to be fair. The selected studies also reported severe adverse events associated with epidural adhesiolysis, including but not limited to dural puncture, neural damage, transient neurological deficits, catheter shearing, and infection.

Strengths of this study include the systematic identification of evidence by independent authors following a pre-defined protocol, evaluation of quality, and assessment of heterogeneity. Limitations were identified in the scarcity and poor methodological quality of literature on epidural adhesiolysis. Also, none of the selected studies assessed efficacy of the procedure beyond 6 months; therefore, long-term clinical utility cannot be determined.

- An update of the aforementioned systematic review was conducted by Helm and colleagues (2013) to evaluate endoscopic epidural adhesiolysis for the treatment of post lumbar surgery syndrome.³ Following the same methodology as described above, the authors identified 4 studies eligible for inclusion (1 randomized controlled trial and 3 observational studies). A fair level of evidence indicates endoscopic lysis of epidural adhesions may be effective for the treatment of chronic low back pain; however, the paucity and poor quality of selected studies does not permit meaningful conclusions.

Randomized Controlled Trials (RCTs)

- In 2013, Gerdesmeyer and colleagues conducted a prospective, multi-center, randomized study to analyze the clinical efficacy of percutaneous epidural lysis of adhesions in chronic radicular pain.⁴ A total of 90 patients were recruited and randomly assigned to receive either percutaneous neurolysis or placebo with concealed allocation in permuted blocks of 4 to 8, stratified by treatment center (n=4), with the use of a computer-generated random list (n=46 neurolysis and n=44 placebo). The study utilized blinding, with patients, outcome assessors, and care providers concealed to the assigned treatment group. Placebo patients had a needle and catheter placed; however, it did not enter the spinal canal and only saline (instead of analgesics) was injected. The primary outcome interest was the difference in percent change of Oswestry Disability Index (ODI) scores 3 months after intervention. Secondary outcome measures included the difference in percent change of ODI scores at 6 and 12 months and the differences in percent change of Visual Analog Scale (VAS) pain scores.

The results at 3, 6, and 12 months indicate the neurolysis procedure was significantly better at improving ODI and VAS scores when compared to the placebo group. The ODI in the lysis group improved from 55.3 to 26.4 compared to 55.4 to 41.8 in the placebo group. The VAS score in the lysis group improved from 6.7 to 2.9 to 6.7 to 4.8 in the placebo group. Procedure-related side effects were common in the neurolysis group, with 34 patients (vs. 20 placebo) reporting pain during the procedure and 42 (vs. 6 placebo) having transient neurologic deficits. Also, two subjects in the treatment group did not undergo lysis because the dura was punctured or the catheter was displaced.

Strengths of this study include the randomized, multi-center design, placebo comparator, and the utilization of blinding techniques. Limitations were identified in the small sample size, lack of objective outcome measures (potential observer bias and/or recall bias), and short follow-up period. Also, the study is reported as “double-blind”; however, the pain physician performing the procedure was aware of the treatment allocation groups (it would be impossible to blind the performing physician) thus it is not a true double-blinded study.

- Five publications by Manchikanti et al. reporting on four randomized controlled trials evaluating epidural adhesiolysis for the treatment of back pain were identified.⁵⁻⁹ Sample sizes ranged from 23 to 120 patients, and participant follow-up varied from 6 months (n=1) to 12 months (n=3) with one study continuing follow-up through 2 years. The primary outcomes of interest included pain and functional status. All studies showed a reduction in pain and improved functional status in patients who underwent lysis of epidural adhesions; however, there was a trend toward decreasing effectiveness with increasing follow-up time and most patients required 2 to 3 lysis procedures per year in order to maintain adequate pain relief.

Strengths of these clinical trials include the randomized controlled design, the extended follow-up through 2 years, and use of a placebo comparator. However, significant limitations were identified in the small sample sizes, recruitment from only one health center, lack of blinding, differences in the placebo and treatment protocols, and the use of subjective outcome measures (potential observer bias and/or recall bias). Also, 2:3 randomization was utilized; thus creating larger treatment blocks and potential bias towards the treatment effect. Lastly, two studies recruited

participants from the same health center during the same time period; therefore, an overlap of study participants could exist.

Nonrandomized Studies

- Manchikanti and colleagues (2012) also conducted a prospective observational study of complications in 10,000 fluoroscopically directed epidural injections; of which, 839 were adhesiolysis procedures.¹⁰ The authors evaluated occurrences of intravascular entry of the needle, return of blood, profuse bleeding, local hematoma, bruising, dural puncture and headache, nerve root or spinal cord irritation with resultant injury, infectious complications, vasovagal reactions, and facial flushing. Intravascular needle entry was highest for the adhesiolysis procedure (11.6%) when compared to other epidural procedures. Adhesiolysis was also associated with return of blood (3.6%), transient nerve root irritation (1.9%), dural puncture (1.8%), and profuse bleeding (1.0%). All other complications of interest were less than 1% for adhesiolysis.
- Two additional observational studies and two case series evaluating lysis of epidural adhesions for the treatment of chronic back pain were identified.¹¹⁻¹⁴ The results suggested epidural adhesiolysis may be effective for the treatment of back pain; however, all studies had significant methodological limitations including, but not limited to, lack of randomization, short follow-up periods, lack of a comparator, lack of objective outcome measurers, and small sample sizes.

EVIDENCE SUMMARY

The evidence is insufficient to support percutaneous or endoscopic lysis of epidural adhesions for the long-term treatment of back pain. Further, good-quality studies are needed to confirm the clinical utility, durability, and safety of epidural adhesiolysis.

CLINICAL PRACTICE GUIDELINES

Colorado Division of Workers' Compensation

The 2014 Colorado Division of Workers' Compensation evidence-based clinical practice guideline for epiduroscopy and epidural lysis of adhesions stated, "studies of epidural lysis demonstrate no treatment pain relief from the procedure. Given the low likelihood of a positive response, the additional costs and time requirement, and the possible complications from the procedure, epiduroscopy, or mechanical lysis, is not recommended."¹⁵

American College of Occupational and Environmental Medicine (ACOEM)

The 2011 evidence-based ACOEM clinical practice guideline on low back disorders gave a Level "I": Insufficient Evidence—Not Recommended for adhesiolysis to treat acute, subacute, or chronic low back pain, spinal stenosis, or radicular pain syndromes.¹⁶

National Institute for Health and Care Excellence (NICE)

The 2010 evidence-based NICE clinical practice guideline on therapeutic endoscopic division of epidural adhesions stated, “current evidence on therapeutic endoscopic division of epidural adhesions is limited to some evidence of short-term efficacy, and there are significant safety concerns.”¹⁷ The guideline went on to recommend this procedure only be used with special arrangements for clinical governance, consent and audit or research.

American Society of Interventional Pain Physicians (ASIPP)

The 2003 (updated 2013) evidence-based ASIPP clinical practice guideline on interventional techniques in chronic spinal pain stated, “the evidence for lumbar percutaneous adhesiolysis is fair for managing chronic low back and lower extremity pain secondary to post surgery syndrome.”¹⁸ The guideline did not address lumbar endoscopic adhesiolysis due to “limited evidence and rare use”. Of note, several authors had conflicts of interest with the epidural adhesiolysis device manufacturers (e.g., Epimed International-manufacturer of the Racz® catheter).

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)

As of 7/29/2020, no Centers for Medicare & Medicaid (CMS) coverage guidance was identified which addresses the lysis of epidural adhesions for the treatment of back pain.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUSMental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

REFERENCES

1. Hayes Inc. *Hayes Health Technology Brief: Percutaneous Epidural Adhesiolysis for Chronic Low Back Pain*. 2018.
https://www.hayesinc.com/subscribers/displaySubscriberArticle.do?articleId=92786&searchStore=%24search_type%3Dall%24icd%3D%24keywords%3DEpidural%2CAdhesiolysis%24status%3Dall%24page%3D1%24from_date%3D%24to_date%3D%24report_type_options%3D%24technology_type_options%3D%24organ_system_options%3D%24specialty_options%3D%24order%3DasearchRelevance. Accessed 12/15/2018.
2. Helm li S, Benyamin RM, Chopra P, Deer TR, Justiz R. Percutaneous adhesiolysis in the management of chronic low back pain in post lumbar surgery syndrome and spinal stenosis: a systematic review. *Pain physician*. 2012;15(4):E435-462.
3. 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*. 2013;16(2 Suppl):Se125-150.
4. 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*. 2013;16(3):185-196.
5. Manchikanti L, Boswell MV, Rivera JJ, et al. [ISRCTN 16558617] A randomized, controlled trial of spinal endoscopic adhesiolysis in chronic refractory low back and lower extremity pain. *BMC anesthesiology*. 2005;5:10.
6. Manchikanti L, Cash KA, McManus CD, Pampati V, Singh V, Benyamin R. 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*. 2009;12(6):E341-354.
7. 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*. 2003;6(3):259-267.
8. Manchikanti L, Singh V, Cash KA, Pampati V. 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. *Journal of pain research*. 2012;5:597-608.
9. Manchikanti L, Singh V, Cash KA, Pampati V, Datta S. A comparative effectiveness evaluation of percutaneous adhesiolysis and epidural steroid injections in managing lumbar post surgery syndrome: a randomized, equivalence controlled trial. *Pain physician*. 2009;12(6):E355-368.
10. Manchikanti L, Malla Y, Wargo BW, Cash KA, Pampati V, Fellows B. A prospective evaluation of complications of 10,000 fluoroscopically directed epidural injections. *Pain physician*. 2012;15(2):131-140.
11. Donato AD, Fontana C, Pinto R, Beltrutti D, Pinto G. The effectiveness of endoscopic epidurolysis in treatment of degenerative chronic low back pain: a prospective analysis and follow-up at 48 months. *Acta neurochirurgica Supplement*. 2011;108:67-73.
12. Pereira P, Severo M, Monteiro P, et al. Results of Lumbar Endoscopic Adhesiolysis Using a Radiofrequency Catheter in Patients with Postoperative Fibrosis and Persistent or Recurrent Symptoms After Discectomy. *Pain practice : the official journal of World Institute of Pain*. 2016;16(1):67-79.
13. Takeshima N, Miyakawa H, Okuda K, et al. Evaluation of the therapeutic results of epiduroscopic adhesiolysis for failed back surgery syndrome. *British journal of anaesthesia*. 2009;102(3):400-407.

14. Akbas M, Elawamy AR, Salem HH, Fouad AZ, Abbas NA, Dagistan G. Comparison of 3 Approaches to Percutaneous Epidural Adhesiolysis and Neuroplasty in Post Lumbar Surgery Syndrome. *Pain physician*. 2018;21(5):E501-E508.
15. Colorado Division of Workers' Compensation: Cervical Spine Injury Medical Treatment Guidelines. *Agency for Healthcare Quality and Research: National Guideline Clearinghouse*. 2014:96.
16. American College of Occupational and Environmental Medicine: Low Back Disorders. *Agency for Healthcare Quality and Research: National Guideline Clearinghouse* 2011.
17. National Institute for Health and Care Excellence: Therapeutic Endoscopic Division of Epidural Adhesions. 2010; <https://www.nice.org.uk/guidance/ipg333/chapter/1-Guidance>. Accessed 06/02/2017.
18. 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*. 2013;16(2 Suppl):S49-283.
19. Cox L, Aaronson D, Casale TB, Honsinger R, Weber R. Allergy immunotherapy safety: location matters! *The Journal of Allergy and Clinical Immunology: In Practice*. 2013;1(5):455-457.
20. Epstein TG, Liss GM, Murphy-Berendts K, Bernstein DI. AAAAI and ACAAI surveillance study of subcutaneous immunotherapy, year 3: what practices modify the risk of systemic reactions? *Annals of Allergy, Asthma & Immunology*. 2013;110(4):274-278. e271.
21. Highsmith MJ, Nelson LM, Carbone NT, et al. Outcomes associated with the Intrepid Dynamic Exoskeletal Orthosis (IDEO): a systematic review of the literature. *Military medicine*. 2016;181(suppl_4):69-76.
22. Peter F. Ullrich J, MD. Scar Tissue and Pain After Back Surgery. 2002; <https://www.spine-health.com/treatment/back-surgery/scar-tissue-and-pain-after-back-surgery>. Accessed 6/3/2017.
23. Services CfMM. Local Coverage Determination (LCD): Non-Covered Services (L35008). 2015; <https://med.noridianmedicare.com/documents/10546/6990983/Non-Covered+Services+LCD>. Accessed 6/4/2017.