Molina Clinical Policy
Percutaneous Epidural Adhesiolysis for Chronic Low Back Pain (RACZ Procedure): Policy No. 257

Last Approval: 6/8/2022
Next Review Due By: June 2023

DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members. References included were accurate at the time of policy approval and publication.

OVERVIEW

Percutaneous epidural adhesiolysis (also known as epidural neurolysis, epidural neuroplasty, lysis of epidural adhesions or racz procedure) is a treatment for chronic back pain that involves disruption, reduction, and/or elimination of fibrous tissue from the epidural space. Lysis of adhesions is carried out by catheter manipulation and/or injection of saline to disrupt the adhesions. Some protocols call for additional injections of steroids, hypertonic saline (10% sodium chloride solution), and/or hyaluronidase into the epidural space to further disrupt the adhesions. Percutaneous adhesiolysis is typically performed by a neurologist, orthopedic surgeon, neurosurgeon, or interventional pain physician on outpatients in an interventional radiology suite. When performed in a single session, the procedure takes less than 1 hour but it can also be performed over a 3-day period. Most patients require more than one adhesiolysis treatment to achieve durable relief of pain, and the procedure can be repeated at 4- to 6-week intervals. Epidural adhesiolysis is intended for patients with chronic back pain with or without radiculopathy that has not responded adequately to noninterventional and nonsurgical conservative modalities, and to fluoroscopically directed epidural injections. Common underlying indications include postlaminectomy syndrome, spinal stenosis, vertebral body compression fracture, disc herniation with radiculitis, and resistant multilevel degenerative arthritis.

COVERAGE POLICY

Percutaneous epidural adhesiolysis for chronic low back pain **is considered experimental, investigational, and unproven** for any indication, due to insufficient clinical evidence of safety and efficacy in published peer reviewed medical literature.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE

The clinical evidence for percutaneous adhesiolysis consists of several randomized controlled trials (RCT's) involving at least 50 patients with chronic back pain with or without radiculopathy that had not responded adequately to conservative therapy for at least 6 months (due to failed back surgery, spinal stenosis, or other spinal disorders). The quality of the overall body of evidence is low. Several studies were performed at the same center, and they have limitations such as fairly high attrition rates, especially in the control groups, insufficient statistical power to establish a safety profile, and inadequate double blinding. The protocols varied across the studies, which complicates comparisons of treatment results. Only one study employed placebo controls, which precludes the determination of an absolute treatment effect based on the data from the other studies. There is a need for additional, longer term well-designed

trials with larger patient populations on this therapy to enable the drawing of more definitive conclusions, and to determine which patients might derive health benefits from this intervention. A summary of the relevant RCT's is provided below.

One of the earliest RCT's conducted by Manchikanti et al. (2004) compared the efficacy and safety of 1-day percutaneous epidural adhesiolysis for the treatment of chronic low back pain in 75 patients with a history of ≥ 1 back surgery or spinal stenosis. The patients were randomized in a double-blind manner to three treatment groups: steroid injection alone with no adhesiolysis (Group I; n=25), epidural adhesiolysis with normal saline and steroid injection (Group II; n=25), or epidural adhesiolysis with hypertonic saline and steroid injection (Group III; n=25). Pain, disability scores, and range of motion improved significantly in the active treatment groups at 3, 6, and 12 months compared with baseline measurements, and compared with controls. At 12 months, 72% of the patients in the Hypertonic Saline group reported significant pain relief (≥ 50%) compared with 60% in the Normal Saline group and 0% of the Control group (P<0.001 for the difference between treatment and controls). On average there was a 41% to 47% improvement in mean pain scores in the active treatment groups versus a 13% improvement in the controls at 12 months. While the results suggest that in this group of patients, percutaneous adhesiolysis resulted in significantly improved pain relief compared with steroid injections, the study sample is small and longer-term follow-up needed.[6]

Veihelmann et al. (2006) compared the efficacy and safety of 1-day percutaneous epidural adhesiolysis with physical therapy in 99 patients with a history of chronic low back pain and sciatica due to disc protrusion/prolapse or failed back surgery; 13 patients had a prior lumbar discectomy. The patients were randomized to percutaneous epidural adhesiolysis and steroid injections (n=47), or physical therapy (n=52) with the option to cross over to the adhesiolysis group after 3 months. Patients who underwent adhesiolysis as their initial treatment mean disability score was 54% better at 3 months versus 50% better at 12 months and mean leg and back pain scores were 67% to 68% better at 3 months versus 61% better at 12 months. While the data suggest that percutaneous adhesiolysis improves short-term outcomes in patients with chronic back pain compared with physical therapy, intergroup differences were not statistically analyzed at 6 or 12 months after treatment due to the loss to follow-up of a high number of patients in the Physical Therapy group.

Manchikanti et al. (2012) reported on outcomes at 2 years for patients treated in their earlier RCT.[7] For this follow up, 54 of 60 patients (90%) from the Adhesiolysis group were available for per protocol (PP) analysis; 6 patients (10%) were unblinded (n=4) or had died (n=2). In the Control group, only 8 patients (13%) were available for PP analysis; 52 patients (87%) were unblinded. However, all patients in both groups were included in an intent-to-treat (ITT) analysis. The primary outcome in this study was defined as ≥50% improvement in pain and ODI scores. During 2 years of follow up, the mean number of procedures were significantly higher in the Adhesiolysis group compared with the Control group (6.4 versus 2.4; P≤0.05). At 2 years, the mean duration of total relief from back pain and leg pain was significantly longer in the Adhesiolysis group compared with the Control group (78.5 versus 14.8 weeks and 77.7 versus 15.0 weeks, respectively; P≤0.05 for each outcome). While this analysis showed that adhesiolysis improved outcomes in patients with post-lumbar surgery low back and extremity pain, there was a high attrition rate particularly in the control group, which makes it difficult to adequately evaluate treatment effects. This study also lacked a placebo control.

In a multicenter, double blind, placebo controlled RCT; Gerdesmeyer et al. (2013) compared the efficacy and safety of percutaneous adhesiolysis for chronic lumbosacral pain and radiculopathy unresponsive to ≥ 4 months of conservative therapy in 90 patients. The ODI and VAS scores as well as the success rates for ODI versus VAS were significantly better at 3 and 6 months and at 1 year in the Adhesiolysis group compared with the Placebo Control group. Adverse events included procedure-related pain in 34 patients (74%) in the Adhesiolysis group compared with 20 patients (45%) in the Placebo Control group. A limitation of this study is the inability to determine how each of the components of treatment contributed to any treatment effect or whether any one of them could be modified or eliminated. High rates of attrition may have also affected analysis of treatment effects. Finally, a placebo effect of treatment cannot be ruled out.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
62263	Percutaneous lysis of epidural adhesions using solution injection (eg, 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 (eg, hypertonic saline, enzyme) or mechanical means (e.g., catheter) including radiologic localization (includes contrast when administered), multiple adhesiolysis sessions; 1 day

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

6/8/2022	Policy reviewed, no changes.
6/9/2021	Policy reviewed, no changes.
4/23/2020	Policy reviewed, updated references.
9/18/2019	Policy reviewed, no changes.
9/13/2018	Policy reviewed, updated references.
6/22/2017	Policy reviewed, no changes.
12/14/2016	Policy reviewed, no changes.
12/16/2015	Policy reviewed, no changes.
10/12/2015	New policy.

REFERENCES

Government Agency

1. Centers for Medicare and Medicaid Services (CMS). Medicare coverage database. Available from CMS.

Evidence Based Reviews and Publications

1. AMR Peer Review. Policy reviewed in January 2020 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the area of Orthopedic Surgery.
2. Hayes. Health technology assessment: Percutaneous epidural adhesiolysis for chronic low back pain. Available from Hayes. Published September 2018. Updated November 2021. Registration and login required.

National and Specialty Organizations

1. Agency for Healthcare Research and Quality (AHRQ). Low back disorders. Updated February 24, 2016.
2. National Institute for Clinical Evidence (NICE). Interventional procedure guidance: Therapeutic endoscopic division of epidural adhesions [IPG333]. Available from NICE. Published February 2010.

Peer Reviewed Publications

1. Choi EJ, Yoo YJ, Lee PB, et al. A retrospective study to evaluate the effect of concentration of hypertonic saline on efficacy and safety of epidural adhesiolysis. Anesth Analg. 2017 Jun;124(6):2021-2029. doi: 10.1213/ANE.0000000000001925.
2. Chun-jing H, Hao-xiong N, jia-xiang N. The application of percutaneous lysis of epidural adhesions in patients with failed back surgery syndrome. Acta Cir Bras. 2012;27(4):357-362.
3. Epter RS, Helm S 2nd, Hayek SM, Benyamin RM, Smith HS, Abdi S. Systematic review of percutaneous adhesiolysis and management of chronic low back pain in post lumbar surgery syndrome. Pain Physician. 2009;12(2):361-378.
4. Gerdesmeyer L, Wagenpfeil S, Birkenmaier C, Veihelmann A, Hauschild M, Wagner K, 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. Helm S, Racz GB, Gerdesmeyer L, et al. Percutaneous and endoscopic adhesiolysis in managing low back and lower extremity pain: A systematic review and meta-analysis. Pain Physician. 2016 Feb;19(2):E245-82.
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7. Manchikanti L, Cash KA et al. Assessment of effectiveness of percutaneous adhesiolysis in managing chronic low back pain secondary to lumbar central spinal canal stenosis. Int J Med Sci. 2013;10(1):50-9. doi: 10.7150/ijms.5303.
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. J Pain Res. 2012;5:597-608.
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10. 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(2):177-186.
11. 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. 2009a;12(6):E341-E354.
12. Manchikanti L, Pampati V, Cash KA. Protocol for evaluation of the comparative effectiveness of percutaneous adhesiolysis and caudal epidural steroid injections in low back and/or lower extremity pain without post surgery syndrome or spinal stenosis. Pain Physician. 2010 Mar-Apr;13(2):E91-E110.
13. Manchikanti L, Abdi S, Atluri S, et al. ASIPP-IPM. 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.
14. Pereira P, et al. Results of lumbar endoscopic adhesiolysis using radiofrequency catheter in patients with postoperative fibrosis and persistent or recurrent symptoms after discectomy. Pain Pract 2016 Jan;16(1):67-79.
15. Rapcan R, Kocan L, Mláka J, et al. A randomized, multicenter, double-blind, parallel pilot study assessing the effect of mechanical adhesiolysis vs adhesiolysis with corticosteroid and hyaluronidase administration into the epidural space during epiduroscopy. Pain Med. 2018 Mar 23. doi: 10.1093/pm/pnx328.
16. Tuijp SJ, Van Zundert J, De Vooght P, et al. Does the use of epiduroscopic lysis of adhesions reduce the need for spinal cord stimulation in failed back surgery syndrome? A short-term pilot study. Pain Pract. 2018 Jan 18. doi: 10.1111/papr.12681.
17. Veihelmann A, Devens C, Trouillier H, Birkenmaier C, Gerdesmeyer L, Refior HJ. Epidural neuroplasty versus physiotherapy to relieve pain in patients with sciatica: a prospective randomized blinded clinical trial. J Orthop Sci. 2006;11(4):365-369.

Other Peer Reviewed and National Organization Publications (used in the development of this policy)

1. Brito-García N, García-Pérez L, et al. Efficacy, effectiveness, safety, and cost-effectiveness of epidural adhesiolysis for treating failed back surgery syndrome. A Systematic Review. Pain Med. 2019 Apr 1;20(4):692-706. doi: 10.1093/pm/pny233.
2. Cho PG, Ji GY, Yoon YS, et al. Clinical effectiveness of percutaneous epidural neuroplasty according to the type of single-level lumbar disc herniation: A 12-month follow-up study. J Korean Neurosurg Soc. 2019 Nov;62(6):681-690. doi: 10.3340/jkns.2019.0070. Epub 2019 Oct 8.
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APPENDIX

Reserved for State specific information. *Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.*