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

Last Approval: 06/11/2025
Next Review Due By: June 2026

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 post-laminectomy syndrome, spinal stenosis, vertebral body compression fracture, disc herniation with radiculitis, and resistant multilevel degenerative arthritis.

Regulatory Status

The RACZ epidural catheter is a class II device that received FDA 510(k) premarket notification approval as a substantially equivalent device on October 8, 1996.

COVERAGE POLICY

Percutaneous epidural adhesiolysis for chronic low back pain is considered **experimental, investigational, and unproven** due to insufficient evidence in the peer-reviewed medical literature to establish long-term safety, efficacy, and effect on net health outcomes.

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 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 drawing more definitive conclusions and determine which patients might derive health benefits from this intervention. A summary of the relevant RCT's is provided below.

Randomized Controlled Trials

Gerdesmeyer et al. (2021) conducted multicenter prospective, randomized, placebo-controlled clinical trial of patients who underwent percutaneous adhesiolysis vs a sham procedure for chronic lumbosacral radicular pain. A total of 90 patients who had failed conservative treatments were enrolled in the 10-year follow up study. Patients were randomly assigned to the adhesiolysis (46) or sham procedure (44) groups. Randomization was concealed; patients, providers and outcome assessors were blind to the treatment group. The primary outcomes were a mean change of the Oswestry Disability Index (ODI) scores and Visual Analogue Scale (VAS) pain score at 1 and 10 years after intervention. A 50% improvement in Oswestry Disability Index (ODI) and Visual Analogue Scale (VAS) pain score was considered clinically relevant. Of the placebo group, 26/44 completed the 1year assessment and 23/44 completed the 10-year assessment. Of the adhesiolysis group, 31/46 completed the 1-year assessment and 29/46 completed the 10-year assessment. A total of 52/90 patients completed the 10-year assessment. At the one-year assessment, 34% (9/26) of the placebo group and 90% (28/31) of the intervention group had a greater than 50 % improvement in the Oswestry Disability Index score ($p<0.01$). For the Visual Analogue Scale (VAS) pain score 69% (18/26) of the placebo group and 93% (29/31) of the intervention group met the clinically relevant benchmark ($p<0.032$). Clinically relevant improvement 10 years after intervention were noted in both the Visual Analogue Scale pain score and the Oswestry Disability Index scores. 65% (15/23) of the placebo group and 90% (25/29) of the intervention group had a greater than 50 % improvement in the Oswestry Disability Index score ($p<0.01$). 69% (16/23) of the placebo group and 86% (25/29) of the intervention group had a greater than 50 % improvement in the Oswestry Disability Index score ($p<0.01$). The 10 years follow up found a sustained placebo effect in patients after a "placebo minimally invasive lysis procedure". The study was limited by lack of imaging at the 10-year assessment, a large variety of unanalyzed noninvasive treatments, changes in patient biometric status, pain tolerance and a large loss of patients to follow up.

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 (Oswestry Disability Index) 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; $P\leq0.05$). 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; $P\leq0.05$ 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 placebo control.

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.

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.

Systematic Reviews and Meta-Analyses
Manchikanti et al. (2023) published a systematic review and meta-analysis of 9 randomized controlled trials (RCT) on the efficacy of percutaneous adhesiolysis for treatment of chromic refractory low back and lower extremity pain. RCTs included patients who had undergone percutaneous epidural neurolysis or adhesiolysis for post-surgery syndrome, central spinal stenosis, or disc herniation, with outcome data for six months. Six of the trials were on post-surgery syndrome (529 subjects), two on spinal stenosis (94 subjects) and one on disc herniation (90 subjects). Eight of the trials were active controlled trials and one trial was placebo controlled. The primary outcome measured was significant reduction in pain, for both short term (up to 6 months) and long term (more than 6 months) assessments. Measurements obtained at 3-, 6- and 12-months post intervention. Clinically important outcome measures were 50% significant improvement from the baseline pain score or a change of at least 3 points on an 11-point pain scale of 0 to 10 and a change of 30% or more on disability scores. Results were reported utilizing dual-arm and single arm meta-analysis for pain and functionality. Assessment of pain levels and functionality were completed at 6 and 12 months utilizing dual-arm and single-arm meta-analyses.

At 6 months the findings for pain and functionality were: The dual arm meta-analysis included 504 patients (272 intervention; 232 control) from seven trials comparing percutaneous adhesiolysis with a control group. The results showed a statistically significant difference in pain levels between these two groups [SMD −1.49 (−2.20, −0.78), p < 0.0001] and a statistically significant difference in functionality levels between these two groups [SMD −1.43 (−2.13, −0.73), p < 0.0001]. The single-arm meta-analysis included 8 trials of patients that underwent percutaneous adhesiolysis. The pooled mean difference of pain scores from the baseline to 6-month follow-up was a 4.420-point decrease (95% CI −4.536 to −4.304, p < 0.0001) and he pooled mean difference of functionality scores from the baseline to 6-month follow-up was a 16.307-point decrease (95% CI –16.875 to –15.739, p < 0.0001). The single-arm meta-analysis with a control group included seven trials, showed the pooled mean difference of pain scores from the baseline to 6-month follow-up was a 2.141-point decrease (95% CI −2.313 to −1.970, p < 0.0001) and the he pooled mean difference of functionality scores from the baseline to 6 month follow-up was a 6.286 point decrease (95% CI −7.097 to −5.475, p < 0.0001).

At 12 months, the findings for pain and functionality were: The dual arm meta-analysis included 362 patients from six trials comparing percutaneous adhesiolysis with a control group. The results showed a statistically significant difference in pain levels between these two groups [SMD −1.71 (−2.19, −1.22),p < 0.0001] and a statistically significant difference in functionality levels between these two groups [SMD −1.65 (−2.09, −1.21), p < 0.0001]. The single-arm meta-analysis included 7 trials of patients that underwent percutaneous adhesiolysis. The pooled mean difference of pain scores from the baseline to 12-month follow-up was a 4.226-point decrease (95% CI: –4.352 to –4.099, p < 0.0001) and the pooled mean difference of functionality scores from the baseline to 12 months follow-up was a 15.881-point decrease (95% CI −16.485 to −15.277, p < 0.0001). The single-arm meta-analysis with a control group included six trials, the pooled mean difference of pain scores from the baseline to 12 months follow-up was a 2.156-point decrease (95% CI −2.409 to −1.904, p < 0.0001) and the pooled mean difference of functionality scores from the baseline to 12 months follow-up was a 5.387-point decrease (95% CI −6.646 to −4.129, p < 0.0001).

Based on the nine RCTs included in this systematic review and meta-analysis (seven high-quality and two moderate-quality RCTs) the authors reported level I – II evidence, with moderate to strong strength of recommendation that percutaneous adhesiolysis is efficacious in the treatment of chronic refractory low back and lower extremity pain after

failure of conservative management and fluoroscopically directed epidural injections. The limitations of this study include paucity of the literature and lack of placebo-controlled trials. The following key summary point is called out by the authors: “Significant paucity of the literature and heterogeneity among available trials continues to be an issue, resulting in an ongoing debate regarding efficacy, effectiveness, indications, and medical necessity”.

Manchikanti et al. (2020) performed a meta-analysis to review the efficacy of percutaneous adhesiolysis to treat low back and lower extremity pain, especially in patients who had surgery of the lumbar spine. Utilization of percutaneous adhesiolysis declined 53.2% between 2009 and 2016; a 10.3% decline is reported annually per 100,000 fee-for-service (FFS) Medicare population. The decline is attributed to non-coverage policies issued by contractors which have led to noncoverage by Medicare Advantage plans, Managed Care plans of Medicaid, and other insurers. Four systematic reviews of percutaneous adhesiolysis were published since 2015 – three demonstrated proper methodology and appropriate results and one poorly performed systematic review showed negative results. The authors concluded that there is level I or strong evidence for the efficacy of percutaneous adhesiolysis for the management of chronic low back and lower extremity pain related to post-lumbar surgery syndrome. The main limitation of this meta-analysis is the conflict of interest in the lead investigator. Manchikani is the founder and current Chairman of the Board and Chief Executive Officer of American Society of Interventional Pain Physicians (ASIPP) and an advocate of use of the RACZ catheter. In the 2023 study summarized above the reviewed RCTs were dated between 1999 and 2018. Study participants varied between 44 and 120 subjects, with 8/9 studies having less than 100 participants enrolled. Of note, Manchikanti was principal investigator on 3 of the RCTs. He is also the lead author of the 2021: Epidural interventions in the management of chronic spinal pain: American Society of Interventional Pain Physicians (ASIPP) comprehensive evidence-based guidelines and principal investigator of the major research on this topic.

Non-Randomized Studies, Retrospective Reviews, and Other Sources of Evidence
Ege (2024) conducted a retrospective cohort study of 72 patients with chronic radicular low back pain to compare the effectiveness of percutaneous neuroplasty in patients with lumbar epidural fibrosis who have and have not had lumbar surgery. These patients had MRI with contrast that showed fibrosis in the epidural region, and a filling defect post epidurogram and epidural neuroplasty. The plan of care and surgical procedures were completed by “the same experienced specialist algologist in the algology clinic” at the Diyarbakir Gazi Yaşargil Health Sciences University. Health Turkiye defines algologists as “doctors who have completed 6 years of medical education must first get specialization training in one of the fields of neurology, physical medicine, and rehabilitation or anesthesiology all of which take 4-5 years. After that, the duration of the Algology specialty training is 2 years”. Using the Visual Analog Scale and the Oswestry Disability Index score, pain and functionality were assessed pre-procedure, and at one- and six-months post neuroplasty. Additionally patient use of opioids, duloxetine and pregabalin were obtained from the medical record at the defined follow up times. Of the 76 patients in the study, 40.7 % had previous lumbar surgery, while 59.2% did not. The Visual Analog Scale and the Oswestry Disability Index scores significantly decreased at one- and sixth-months post procedure. Medication use was also found to be significantly decreased at one- and six-months post procedure. The author concluded that “percutaneous epidural neuroplasty is a safe and effective treatment method for patients with lumbar epidural fibrosis”. Patients who did not a history of previous lumbar surgery had a more significant decrease in the VAS score at one month than patients with a previous lumbar surgery. The procedure could be repeated for incomplete pain control, as it is minimally invasive, with few complications and is performed under local anesthesia. Limitations of the study were the retrospective design and lack of long-term follow up. “Prospective large-scale randomized studies are needed to establish the efficacy of caudal neuroplasty-adhesiolysis procedure”.

Manchikanti et al. (2021) analyzed declining utilization patterns of percutaneous adhesiolysis procedures in the Fee-For-Service (FFS) Medicare population. The authors note a significant decline in utilization of these procedures; between 2009 and 2018 there was a decrease of 69.2% (annual rate decrease of 12.3%). To further the decline, there was an increase of interventional techniques between 2009 and 2018 in the population. Conversely from 2000 to 2009, there was an increased utilization of 62.6% for these procedures (annual rate increase of 5.6%). There has been significant published evidence for all interventional techniques, specifically percutaneous epidural adhesiolysis. This includes randomized controlled trials (RCTs), systematic reviews, cost utility analysis, and evidence for real world scenarios. Evidence focuses on the management of chronic recalcitrant low back pain secondary to post-surgery syndrome, spinal stenosis, and disc herniation. Decreased utilization can be contributed to the approach of the Affordable Care Act, misunderstanding of evidence-based medicine, a lack of local coverage determinations (LCDs) and LCDs without coverage, non-coverage by various insurers, and multiple other regulations.

Hayes (2022) published a Health Technology Assessment on Percutaneous Epidural Adhesiolysis for Chronic Low Back Pain. Six RCTs were analyzed with sample sizes between 50 to 120 patients. Pain was reported using a numerical scale of 1-10 or visual analog scale and function (reported as Oswestry Disability Index [ODI]) – lower scores were indicative of better function. Clinically relevant pain relief was classified as a ≥ 50% reduction from baseline and clinically relevant functional improvement as a ≥ 40% or ≥50% reduction from baseline of the applicable study. There is a small body of low-quality evidence supporting the use of percutaneous epidural adhesiolysis citing improved function and pain relief. No major complications were reported. The author notes that evidence is minimal regarding the comparison of adhesiolysis with physical therapy. In some patients, to maintain benefits the adhesiolysis procedure must be repeated more than one time a year. Further research is needed on the differential efficacy of percutaneous epidural adhesiolysis based on patient and clinical characteristics – this information could aid in patient selection. Additional long-term studies focused on optimized patient follow-up can evaluate patient safety and the endurance of the procedure and need for additional treatments.

National and Specialty Organizations

The **American Society of Interventional Pain Physicians (ASIPP)** published comprehensive evidence-based guidelines on *Epidural Interventions in the Management of Chronic Spinal Pain*. Guidance included focuses on performing therapeutic epidural procedures, including caudal, interlaminar in lumbar, cervical, and thoracic spinal regions, transforaminal in lumbar spine, and percutaneous adhesiolysis in the lumbar spine. Evidence for percutaneous epidural adhesiolysis in managing disc herniation was reported in a RCT – there is a moderate to strong recommendation for long-term improvement in patients nonresponsive to conservative management and fluoroscopically guided epidural injections. Evidence for percutaneous epidural adhesiolysis in lumbar stenosis is based on moderate to high quality RCTs, observational studies, and systematic reviews – there is a strong recommendation for long-term improvement after failure of conservative management and fluoroscopically guided epidural injections. Percutaneous epidural adhesiolysis has shown long-term improvement following failure of conservative management and fluoroscopically guided epidural injections (Manchikanti et al. 2021). Of note, the principal investigator of the major research in this topic also wrote this guideline.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	Description
62263	Percutaneous lysis of epidural adhesions using solution injection (e.g., 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 (e.g., 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

06/11/2025	Policy reviewed, no changes to coverage criteria. Summary of medical evidence reordered.
06/12/2024	Policy reviewed, no changes to coverage, updated overview, summary of medical evidence reordered, IRO Peer Review on May 9, 2024 by a practicing physician board-certified in Orthopaedic Surgery.
06/14/2023	Policy reviewed, no changes to coverage, updated Summary of Medical Evidence section.
06/08/2022	Policy reviewed, no changes.
06/09/2021	Policy reviewed, no changes.

04/23/2020	Policy reviewed, updated references. IRO Peer Review in April 2020 by a practicing, board certified physician with a specialty in Orthopedic Surgery.
09/18/2019	Policy reviewed, no changes.
09/13/2018	Policy reviewed, updated references.
06/22/2017	Policy reviewed, no changes.
12/14/2016	Policy reviewed, no changes.
12/16/2015	Policy reviewed, no changes.
10/12/2015	New policy.

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