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

Last Approval: 6/14/2023
Next Review Due By: June 2024

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.

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 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.

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 (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≤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 placebo control.

Manchikanti, Kosanovic, 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.

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.

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, Knezevic 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) Codes

CPT	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

06/14/2023	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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