Subject: Percutaneous Epidural Adhesiolysis for Chronic Low Back Pain (RACZ Procedure)		Original Effective Date: 10/12/15
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.[1]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

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.

POSITION STATEMENT

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

SUMMARY OF MEDICAL EVIDENCE [4-20]

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 is 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. [11]

Manchikanti et al. (2012) [8] 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. [8]

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. [4]

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

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

HCPCS	Description
	N/A

ICD-10	Description: [For dates of service on or after 10/01/2015]
	Any/All

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Government Agency

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Other Resources

2. Hayes a Division of TractManager. Winifred Hayes Inc. Lansdale, Pa
   - Health Technology Assessment. Percutaneous Epidural Adhesiolysis for Chronic Back Pain. Dec, 2014. Archived Jan, 2017.
   - Health Technology Assessment. Percutaneous Epidural Adhesiolysis for Chronic Low Back Pain. Sept, 2018. Updated Jan, 2021.
3. Other Guidelines:
   - EviCore Comprehensive Musculoskeletal Management Guidelines. Accessed at: https://www.evicore.com/provider/clinical-guidelines
   - AIM's Clinical Appropriateness Guideline. Musculoskeletal Program. Interventional Pain Management. Accessed at: https://aimspecialtyhealth.com/resources/clinical-guidelines/musculoskeletal/

Peer Reviewed Publications

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2020-2021 Update:

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IRO Peer Review

31. Advanced Medical Review (AMR): Policy reviewed by practicing MD board certified in Orthopaedic Surgery. 1/16/20

REVIEW/REVISION HISTORY

10/12/15: New Policy
12/16/15, 12/14/16, 6/22/17: Policy reviewed, no changes
9/13/18: Policy reviewed, no changes to the criteria, procedure remains experimental, investigational and unproven. Updated references and guidelines.
9/18/19: Policy reviewed, no changes.
4/23/20: Policy reviewed, no changes to the criteria, procedure remains experimental, investigational and unproven. Updated references and guidelines.
6/9/21: Policy reviewed, no changes to criteria.