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Original Effective Date: 11/15/00

Reviewed: 09/26/24

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Subject: Lysis of Epidural Adhesions

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Lysis of epidural adhesions, also called the Racz procedure, has been investigated as a treatment option for epidural fibrosis and other conditions. The Racz procedure involves the passage of a fluoroscopically guided catheter (the Racz catheter), inserted either endoscopically or percutaneously, and the use of epidural injections of hypertonic saline in conjunction with corticosteroids and analgesics. Theoretically, the use of hypertonic saline results in a mechanical disruption of the adhesions. The saline may also function to reduce edema within previously scarred and/or inflamed nerves. Finally, manipulating the catheter at the time of the injection may disrupt adhesions. Spinal endoscopy has been used to guide the lysis procedure, but the procedure is more commonly performed percutaneously using epidurography to guide catheter placement and identify non-filling adhesions that indicate epidural scarring. In some situations, the catheter may remain in place for several days for serial treatment sessions.

Summary and Analysis of Evidence: Kose, akkaya (2023) set out to assess the effectiveness of percutaneous adhesiolysis (PEA) in patients with chronic lumbar radicular pain refractory to epidural steroid injections, and to determine predictive factors, including demographic, clinical, and procedural data, to provide superior treatment efficacy. One hundred and ninety-three patients were reviewed. Successful treatment outcome was described as a 50% reduction in the visual analog scale score. Among the 193 patients, 109 (56.2%) exhibited a positive treatment response at 12 months. In multivariate logistic regression analysis, no depression, no spondylolisthesis, no previous lumbar surgery, mild foraminal stenosis, no opioid use, and baseline pain scores were the predictive factors significantly associated with unsuccessful treatment outcome. The authors concluded that PEA is a useful treatment option for patients with chronic lumbar radicular pain refractory to epidural steroid injections, and that a history of lumbar surgery, spondylolisthesis, depression, and severe foraminal stenosis could be associated with a poor prognosis. Limitations of this study included that the regression analyses used

were focused on assessing the influence of predictive factors on outcomes at the 12th month; the ability to predict successful outcomes over the longer period remains uncertain. In addition, the success of the treatment was confined solely to changes in pain relief. Due to the lack of routine recording in the clinic, they were unable to track changes in pain medication consumption or functional disability. Also, as with many retrospective studies, there were patients who had to be excluded due to missing data. Finally, they noted that this study was conducted retrospectively, lacking a control or sham group for a comparative analysis of the procedure's outcomes. The prevalence of placebo and nocebo effects in the context of interventional treatments was estimated to range between 13% and 30% and 3% and 8%, respectively.

Gerdesmeyer et al, 2021 published 10 year follow-up results from a previous randomized controlled trial (RCT). After a 4 year enrollment phase, 381 patients with chronic radicular pain persisting beyond 4 months, who failed conservative treatments, were screened. Ninety patients were enrolled. Patients were randomly assigned to receive percutaneous epidural lysis of adhesions or placebo with concealed allocation in permuted blocks of 4 to 8 patients each, and stratified by treatment center. The primary outcomes were a mean change of the Oswestry Disability Index (ODI) scores and Visual Analog Scale (VAS), one and 10 years after intervention. For each rating scale an analysis of variance with the within-patient factor time (baseline, one year follow-up, 10 year follow-up) and the between-patient factor treatment (lysis, placebo) was used. The ODI and VAS scores were significantly better one and 10 years in the lysis group vs the control group. The ODI in the lysis group improved from 55.3 ± 11.6 to 9.6 ± 9.3 after one year and to 11.7 ± 14.2 after 10 years. The placebo group also improved from 55.4 ± 11.5 to 30.7 ± 14.2 after one year and to 24.8 ± 12.0 after 10 years. The VAS improved from 6.7 ± 1.1 to 1.2 ± 1.1 after one year and to 1.5 ± 1.4 after 10 years in the lysis group and from 6.7 ± 1.1 to 2.8 ± 1.5 after one year and to 2.9 ± 1.3 after 10 years after placebo intervention. No treatment-related severe adverse effects occurred within the 10 years, but minor transient neurological effects were seen directly after the intervention. The authors concluded that the 10 year follow-up demonsrated efficacy of the minimally invasive percutaneous adhesiolysis procedure for patients with chronic lumbosacral radicular pain, and that this procedure should be considered as the first treatment option for patients with chronic lumbosacral radicular pain. Several limitations were acknowledged by the authors, including 1) that the long-term effects of single treatment components cannot be specified as no imaging examination was performed at 10 year follow-up; 2) a large variety of unanalyzed noninvasive treatments were done within the 10 years; 3) some participants did not clearly remember the intervention after 10 years; and 4) uncontrolled effects such as higher inhomogeneity of biometric properties, concomitant therapies, pain tolerance level, or just social effects could occur, but were not analyzed in the trial.

Cho et al, 2019 studied whether the outcomes of percutaneous epidural neuroplasty (PEN) are influenced by the type of lumbar disc herniation (LDH), and set out to evaluate the effectiveness of PEN in patients with single-level LDH. This study included 430 consecutive patients with single-level LDH who underwent PEN. Before treatment, the LDH type was categorized as bulging, protrusion, extrusion, and sequestration, while Pfirrmann grades were assigned according to imaging findings. Visual analog scale (VAS) scores for back and leg pain and success rates (Odom's criteria) were assessed at 1, 3, 6, and 12 months after treatment. The mean preoperative VAS scores for back and leg pain were 6.90 and 4.23, respectively; these decreased after PEN as follows: 2.25 and 1.45, respectively, at 1 month; 2.61 and 1.68, respectively, at 3 months; 2.28 and 1.48, respectively, at 6 months; and 2.88 and 1.48,

respectively, at 12 months. The decrease in VAS scores for leg pain was significantly greater in the extrusion and sequestration groups than in the other two groups; there were no other significant differences among groups. More than 70% patients exhibited good or excellent 12-month outcomes according to Odom's criteria. Subsequent surgery was required for 59 patients (13.7%), with a significantly higher rate in the extrusion (25.0%) and sequestration (30.0%) groups than in the bulging (7.3%) and protrusion (13.8%) groups. Nevertheless, subsequent surgery was not required for >70% patients with extrusion or sequestration. Patients with Pfirrmann grades 1-3 (14.0-21.5%) showed a significantly higher rate of subsequent surgery than those with Pfirrmann grade 0 (4.9%). The authors concluded their findings suggest that PEN is an effective treatment for back and leg pain caused by single-level LDH, with the outcomes remaining unaffected by the LDH type. They noted several study limitations, including 1) it was a retrospective analysis; 2) a control group was not included for comparison, so improved clinical outcomes after PEN could not be distinguished from the natural course of LDH; 3) the distribution of patients according to the level and type of LDH was uneven, and this may have affected the statistical results, and 4) this study did not take the MRI after procedure for checking the spontaneous regression of disc (this regression can affect the PEN effect according the disc type).

Manchikanti et al, 2012 studied 120 participants who were randomly assigned to two groups with a 2-year follow-up. Group I (control group, n = 60) received caudal epidural injections with catheterization up to S3 with local anesthetic (lidocaine 2%, 5 mL), nonparticulate betamethasone (6 mg, 1 mL), and 6 mL of 0.9% sodium chloride solution. Group II (intervention group, n = 60) received percutaneous adhesiolysis of the targeted area, with targeted delivery of lidocaine 2% (5 mL), 10% hypertonic sodium chloride solution (6 mL), and nonparticulate betamethasone (6 mg). The multiple outcome measures included the Numeric Rating Scale, the Oswestry Disability Index 2.0, employment status, and opioid intake with assessments at 3, 6, 12, 18, and 24 months posttreatment. Primary outcome was defined as 50% improvement in pain and Oswestry Disability Index scores. Significant improvement with at least 50% relief with pain and improvement in functional status was illustrated in 82% of patients at the 2-year follow-up in the intervention group compared to 5% in the control group receiving caudal epidural injections. The average number of procedures over a period of 2 years in Group II was 6.4 ± 2.35 with overall total relief of approximately 78 weeks out of 104 weeks The authors concluded that this study demonstrated significant improvement in 82% of patients over a period of 2 years with an average of six to seven procedures of 1-day percutaneous adhesiolysis in patients with failed back surgery syndrome. The authors acknowledged several study limitations, including that given the subjective outcome of pain relief, an equivalence study with no placebo/sham control is difficult to interpret; and, there was a large control group dropout rate (n=43 in control group; n=3 in intervention group) at 12 months.

UpToDate review “Subacute and chronic low back pain: Surgical treatment” (Chou, 2024) states that therapies for subacute and chronic low back pain have included adhesiolysis (injection of isotonic saline, hypertonic saline, or hyaluronidase into the epidural space in order to facilitate lysis of adhesions); howevert, “randomized trials for these interventions are not available or inconclusive”.

POSITION STATEMENT:

Catheter-based techniques for lysis of epidural adhesions, with or without endoscopic guidance, used alone or in combination with injection of hypertonic solutions (e.g., saline, corticosteroids, analgesics, hyaluronidase) are considered **experimental or investigational**. Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

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 (**investigational**)
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 (**investigational**)
62280	Injection/infusion of neurolytic substance (eg, alcohol, phenol, iced saline solutions), with or without other therapeutic substance; subarachnoid (**investigational**)
62281	Injection/infusion of neurolytic substance (eg, alcohol, phenol, iced saline solutions), with or without other therapeutic substance; epidural, cervical or thoracic (**investigational**)
62282	Injection/infusion of neurolytic substance (eg, alcohol, phenol, iced saline solutions), with or without other therapeutic substance; epidural, lumbar, sacral (caudal) (**investigational**)

REIMBURSEMENT INFORMATION:

Refer to sections entitled **POSITION STATEMENT** and **PROGRAM EXCEPTIONS**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products: No National Coverage Determination (NCD) and/or Local Coverage Determination (LCD) were found at the time of the last guideline review date.

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

Adhesion: a fibrous band or structure by which parts abnormally adhere.

Arachnoiditis: Inflammation of the middle layer of membranes covering the brain and spinal cord. Arachnoiditis can occur as a complication of procedures such as myelograms, spinal operations, epidural steroid injections, and injury to the spine.

Epidural: outside the dura mater (outermost, toughest, most fibrous of the three membranes covering the brain and spinal cord); the space between the bony vertebral canal and the dura mater (the spinal cord does not fill the bony vertebral canal). The space remaining between the dura mater and the bone of the vertebra is the epidural space.

Fluoroscopy: a radiographic technique in which an object, such as the human body, is examined visually in real time by transmitting X-rays through the object onto a fluorescent screen. The resulting picture on the screen is made up of shadows created by the transmission of different amounts of X-rays through body structures of varying depth and size.

Hypertonic: a solution with a higher salt concentration than in normal cells of the body and the blood.

Lysis: destruction; rupture of cell membrane and loss of cytoplasm.

Neurolysis: destruction of nerve tissue, freeing of a nerve from inflammatory adhesions.

Percutaneous: performed through the skin.

Radiculopathy: any disease of the spinal nerve roots and spinal nerves.

RELATED GUIDELINES:

None applicable.

OTHER:

Other names used to report Percutaneous Lysis of Epidural Adhesions:

Epidural Adhesiolysis
Epidural Neurolysis
Epidurolysis
Hypertonic Saline Injections
Injections, Epidural, Hypertonic Saline
Lysis of Epidural Adhesions
Neurolysis, Epidural
Percutaneous Epidural Neuroplasty
Racz Procedure

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 09/26/24.

GUIDELINE UPDATE INFORMATION:

11/19/00	Outpatient Pain Management Medical Coverage Guideline #02-61000-01 approved by MPCC.
09/15/03	Developed separate Medical Coverage Guideline for Lysis of Epidural Adhesions from Outpatient Pain Management 02-61000-01.
02/15/04	Revised Medical Coverage Guideline. Added additional statements regarding non-coverage for Epiduroscopy and Program Exception for Medicare and More.
09/15/04	Review and revision of guideline; consisting of updated references and various formatting changes. No change to investigational status.
11/15/04	Revision of guideline; consisting of adding an investigational statement for Spinal Endoscopy.
09/15/05	Review and revision of guideline; consisting of updated references.
09/15/06	Review and revision of guideline consisting of updated references.
11/15/06	Revision of guideline.
07/15/07	Annual review; investigational status maintained, guideline reformatted, references updated.

09/15/08	Review and revision of guideline consisting of updated references.
01/01/09	Annual HCPCS coding update: deleted code 0027T.
09/15/09	Scheduled review; no change in position statement. Update references.
08/15/10	Annual review: position statements maintained and references updated.
08/15/12	Scheduled review. Revised description section. Position statement maintained. Deleted CPT code 72275. Updated references.
10/15/13	Scheduled review. Position statement maintained. Revised program exceptions section and updated references.
06/15/14	Revision; added codes 62280, 62281 and 62282.
08/15/19	Scheduled review. Revised description, definitions, and program exceptions. Maintained position statement and updated references.
12/15/20	Scheduled review. Revised description, maintained position statement, and updated references.
09/15/22	Scheduled review. Maintained position statement and updated references.
05/25/23	Update to Program Exceptions section.
01/01/24	Position statements maintained.
10/15/24	Scheduled review. Revised description, maintained position statement and updated references.