MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**Lysis of Epidural Adhesions (Epidural Adhesiolysis)**
Policy Number	**7.01.73**
Category	**Technology Assessment**
Original Effective Date	**03/16/06**
Committee Approval Date	**03/15/07, 02/21/08, 01/15/09, 01/21/10, 12/16/10, 12/15/11, 12/20/12, 12/19/13, 12/18/14, 12/17/15, 11/17/16, 11/16/17, 6/21/18, 12/20/18, 12/19/19, 12/17/20, 12/16/21, 12/22/22, 12/21/23**
Current Effective Date	**12/21/23**
Archived Date	**12/21/23**
Archive Review Date	**N/A**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

POLICY STATEMENT

Based upon our criteria and assessment of the peer-reviewed literature, lysis of epidural adhesions or epidural adhesiolysis performed either by catheter-based techniques or endoscopically as a treatment for back pain, has not been medically proven to be effective and, therefore, is considered **investigational.**

Refer to Corporate Medical Policy #11.01.03 Experimental and Investigational Services

DESCRIPTION

Lysis of epidural adhesions or epidural adhesiolysis (also called epidurolysis, epidural neurolysis, epidural decompressive neuroplasty, percutaneous epidural neuroplasty and Racz neurolysis), using fluoroscopic guidance, with epidural injections of hypertonic saline in conjunction with steroids and analgesics, has been investigated as a treatment option for epidural fibrosis with or without adhesive arachnoiditis. These conditions most commonly occur as a complication of spinal surgery and may be included under the diagnosis of failed back surgery syndrome (FBSS).

Various protocols for lysis of epidural adhesions have been described. In some situations, the catheter may remain in place for several days for serial sessions, as with the Racz procedure, which is performed in an inpatient setting. These procedures may also involve spinal endoscopy to visualize the adhesions and guide the lysis procedure.

RATIONALE

The Racz epidural catheter received Section 510(k) premarket clearance from the U.S. Food and Drug Administration (FDA) in 1996.

There is insufficient evidence to demonstrate the safety, efficacy, and long-term outcomes of LOA. There is currently no evidence that this procedure is as effective as other established interventions for the treatment of back pain. Well-designed, controlled studies comparing lysis of epidural adhesions to alternative treatment are needed.

A small (75 subjects), single center, randomized, controlled study published by Manchikanti et al. in 2004, though adequately designed and reporting positive results, provided insufficient evidence to conclude that lysis of epidural adhesions provides a health benefit. The effectiveness of the study's blinding is not clear, and interpretation of results is limited, because data for 19 patients in the control and three patients in each treatment arm were carried forward from the three-month or six-month evaluation and reported in 12-month outcomes.

E. Hsu et al. (2014) conducted a multi-center, retrospective study of 115 patients who underwent lysis of adhesions for FBSS (n = 104) or spinal stenosis (n = 11) between 2004 and 2007. Twenty-seven demographic, clinical, and procedural variables were extracted from medical records and correlated with the outcome, defined as 50% pain relief or greater lasting one month or more. Overall, 48.7% of patients experienced a positive outcome. Those who had a positive outcome were older (mean age 64.1 years; P = 0.02), while higher baseline numerical rating scale pain scores were associated with a negative outcome (mean 6.7 years; P = 0.07). Use of hyaluronidase did not correlate with outcomes (P = 0.65). In multi-variable analysis, patients age 81 years and older, baseline numerical rating scale score 9 or less (P = 0.02), and patients on or seeking disability or worker's compensation (P = 0.04), were significantly more likely to experience a positive outcome. The authors concluded that patient selection for lysis of epidural adhesions may increase outcomes, but that further research is required.

A two-year follow-up of a randomized, controlled trial (RCT) with 120 patients treated for FBSS has been reported by Manchikanti and colleagues. Patients were assigned to receive either caudal epidural injections or percutaneous adhesiolysis. Outcome measures included Oswestry Disability Index, employment status, and opioid intake. The authors reported that 82% of patients receiving adhesiolysis had significant improvement in functional status and relief of pain by at least 50%, compared to only 5% improvement in the epidural corticosteroid injection group. If patients had improved functioning and pain reductions of at least 50% for at least three months following adhesiolysis, repeat adhesiolysis was permitted. Patients in the adhesiolysis group received an average of 6.4 adhesiolysis procedures, while patients in the epidural corticosteroid injection group averaged 2.4 procedures over the two-year period. Limitations of the study include inadequate blinding, lack of a placebo group, and a high proportion of patient withdrawals.

In 2016, Pereira and colleagues published the results of a small case series study involving 24 subjects with epidural scar tissue following lumbar discectomy who were treated with a combination of different techniques. The techniques used were dependent on the consistency of the fibrous tissue found in each subject. Mild adhesions were lysed by distention of the epidural space with small boluses of saline solution and by mechanical dissection with the tip of a Fogarty catheter. Denser areas of fibrosis were treated by manipulating the inflated balloon of the Fogarty catheter or removing them with a 1 mm flexible endoscopic grasping forceps if no blood vessels could be identified in the vicinity. The thickest and hardest fibrotic areas were initially treated with Fogarty catheter, followed by radiofrequency ablation. All subjects received epidural steroids and anesthetic injection following surgical treatment. One subject reported no improvement at one month and withdrew from the study; all other subjects were followed for 12 months. The authors reported a statistically significant improvement in low back and lower limb pain at all assessment periods up to 12 months ($p<0.0001$ for all). A pain relief over 50% was achieved in 71% of the participants at one month, 63% at three and six months, and 38% at 12 months. Measures on the Oswestry Disability Index were significantly improved at the 15-day, 30-day, and 90-day time points ($p<0.001$, 0.001, and 0.019, respectively). One subject developed facet joint pain distinct from the pre-intervention pain at six months post treatment and underwent medial branch radiofrequency neurotomy with pain relief. No other percutaneous interventions were performed in any other subjects. One subject reported neck pain after irrigation of the epidural space, which resolved spontaneously. Another subject presented with an S1 sensory deficit following the procedure, with full recovery within 48 hours. No infections, additional neurological deficits, dural tears, or any other complications related to the procedure were noted. This small, unblinded, uncontrolled study has multiple methodologic flaws that prevent adequate assessment of the efficacy of lysis of epidural adhesions.

Brito-García et al. (2019) assessed the efficacy, safety, effectiveness, and cost-effectiveness of epidural adhesiolysis for treating patients with chronic pain attributed to FBSS in a systematic review of the literature. Out of the studies that met the inclusion criteria, only two of them were RCTs which included a total of 212 participants; the other seven studies were

observational. The authors assessed that even though the results from both RCTs had a favorable outcome for adhesiolysis, there was a high risk of bias and serious methodology flaws in the studies which included lack of blinding for participants, informing the participants of which treatment they had received and a high dropout rate. The observational studies were of low quality and did not provide any data indicating positive clinical development. The authors concluded the evidence on the efficacy and safety for adhesiolysis is insufficient in patients with FBSS and that further high quality RCTs should be done to assess for efficacy, effectiveness and cost.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

CPT Codes

Code	Description
62263 **(E/I)**	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 **(E/I)**	1 day
62280 **(E/I)**	Injection/infusion of neurolytic substance (e.g., alcohol, phenol, iced saline solutions), with or without other therapeutic substance; subarachnoid
62281 **(E/I)**	Injection/infusion of neurolytic substance (e.g., alcohol, phenol, iced saline solutions), with or without other therapeutic substance; epidural, cervical or thoracic
62282 **(E/I)**	Injection/infusion of neurolytic substance (e.g., alcohol, phenol, iced saline solutions), with or without other therapeutic substance; epidural, lumbar, sacral (caudal)

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HCPCS Codes

Code	Description
No code(s)	

ICD10 Codes

Code	Description
Numerous	

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*Key Article

KEY WORDS

Adhesiolysis, Adhesions, Epidural, Epidurolysis, Lysis, Neurolysis, Percutaneous Adhesiolysis, Racz procedure.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

Based on our review, lysis of epidural adhesions is not addressed in National or Regional Medicare coverage determinations or policies.