MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**LYSIS OF EPIDURAL ADHESIONS**
Policy Number	**7.01.73**
Category	**Technology Assessment**
Effective Date	**03/16/06**
Revised 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**
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 product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare 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.*

POLICY STATEMENT

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

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Lysis of epidural adhesions (also called adhesiolysis, 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 syndrome."

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 visually address the adhesions.

RATIONALE

The Racz epidural catheter received 510(K) premarket notification from the FDA in 1996.

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

A single small (75 subjects), single center randomized controlled study (Manchikanti, et al) published in 2004, though adequately designed and reporting positive results, provides insufficient evidence to conclude that epidural lysis of adhesions provides a health benefit. The effectiveness of blinding is not clear and interpretation of results is limited

because data for 19 patients in the control and 3 patients in each treatment arm were carried forward from the 3 or 6 month evaluation and used to report 12 month outcomes.

E Hsu, et al. (2014) performed a multicenter, retrospective study in 115 patients who underwent lysis of adhesions (LOA) 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 lasting ≥1 month. 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 multivariable analysis, age ≥81 years, baseline numerical rating scale score ≤9 (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 epidural LOA may increase outcomes, but that further research is required.

A 2-year follow-up of a RCT study with 120 patients treated for failed back surgery syndrome has been reported. Patients were assigned to receive either caudal epidural injections or percutaneous adhesiolysis. Outcome measures included Oswestry disability index, employment status and opioid intake. Manchikanti and colleagues reported 82% of patients receiving adhesiolysis had significant improvement in functional status and relief of pain of 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 3 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 2-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 1 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 1 month, 63% at 3 and 6 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 6 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 complication related to the procedure was noted. This small, unblinded or controlled study has multiple methodologic flaws which prevent adequate assessment of the efficacy of epidural lysis of adhesions.

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.*

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)**	limited to 1 day only
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)

HCPCS Codes

Code	Description
No code(s)	

ICD10 Codes

Code	Description
Numerous	

REFERENCES

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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.