



Louisiana

Lysis of Epidural Adhesions

Policy # 00037

Original Effective Date: 07/28/2003

Current Effective Date: 08/10/2020

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers catheter-based techniques for lysis of epidural adhesions, with or without endoscopic guidance, to be **investigational**.*

Note: Techniques used either alone or in combination include mechanical disruption with a catheter and/or injection of hypertonic solutions with corticosteroids, analgesics, or hyaluronidase.

Background/Overview

Epidural Fibrosis and Adhesive Arachnoiditis

Epidural fibrosis with or without adhesive arachnoiditis most commonly occurs as a complication of spinal surgery and may be included under the diagnosis of "failed back surgery syndrome". Both conditions result from the manipulation of the supporting structures of the spine. Epidural fibrosis can occur in isolation, but adhesive arachnoiditis is rarely present without associated epidural fibrosis. Arachnoiditis is most frequently seen in patients who have undergone multiple surgical procedures.

Epidural fibrosis and adhesive arachnoiditis are related to inflammatory reactions that result in the entrapment of nerves within dense scar tissue, increasing the susceptibility of the nerve root to compression or tension. The condition most frequently involves the nerves within the lumbar spine and cauda equina. Signs and symptoms indicate the involvement of multiple nerve roots and include low back pain, radicular pain, tenderness, sphincter disturbances, limited trunk mobility, muscular spasm or contracture, and motor-sensory and reflex changes. Typically, pain is characterized as constant and burning. In some cases, pain and disability are severe, leading to analgesic dependence and chronic invalidism.

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Treatment

Lysis of epidural adhesions, also called the Racz procedure, has been investigated as a treatment option. 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 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 nonfilling adhesions that indicate epidural scarring. Using endoscopy guidance, a flexible fiberoptic catheter is inserted into the sacral hiatus, providing 3-dimensional visualization to steer the catheter toward the adhesions. With the increased visualization, the catheter is more apt to precisely place the injectate in the epidural space and onto the nerve root. Various protocols for lysis have been described; in some situations, the catheter may remain in place for several days for serial treatment sessions.

Endoscopic epidurolysis is also being investigated to treat degenerative chronic low back pain, including spondylolisthesis, stenosis, and hernia associated with radiculopathy. Along with mechanical adhesiolysis, hyaluronidase, ciprofloxacin, and ozone have been applied.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Lysis of epidural adhesions is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

Rationale/Source

Lysis of epidural adhesions involves passing a catheter, either endoscopically or percutaneously, under fluoroscopic guidance into the epidural space to break up adhesions and reduce pain and inflammation.

For individuals who have epidural adhesions who receive lysis, the evidence includes randomized controlled trials. The relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Several randomized controlled trials have reported

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benefits for epidural lysis of adhesions compared with placebo treatment. Many of these trials were conducted at the same center. The interpretation of these trials is limited by differences in patients, populations, and treatment protocols. The treatment for lysis of adhesions varied in the use of mechanical disruption, the type of lytic medications used, and the number of injections given. There was also a large effect in the placebo group, raising questions whether some component of the placebo treatment may be therapeutic. Larger trials with standardized treatment protocols would help determine whether specific treatment protocols have beneficial effects in specific patient populations. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Practice Guidelines and Position Statements

American Society of Interventional Pain Physicians

The American Society of Interventional Pain Physicians (2013) updated its practice guidelines on the management of chronic spinal pain. The guidelines stated that “for lumbar percutaneous adhesiolysis, the evidence is fair in managing chronic low back and lower extremity pain secondary to postsurgery syndrome and spinal stenosis.” Percutaneous adhesiolysis was recommended, “after failure of conservative management of physical therapy, chiropractic, drug therapy, structured exercise program, and fluoroscopically directed epidural injections.” The guidelines also indicated that spinal epidural endoscopic adhesiolysis was not discussed because there is limited evidence; moreover, the procedure is rarely used. The studies cited in the guidelines were evaluated for this evidence review.

American Pain Society

The American Pain Society’s (2009) clinical practice guidelines on interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain did not discuss or draw conclusions on adhesiolysis. The guidelines stated that “for other interventions or specific clinical circumstances, the panel found insufficient evidence from randomized controlled trials to reliably judge benefits or harms.”

U.S. Preventive Services Task Force Recommendations

Not applicable.

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Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some currently unpublished trials that might influence this review are listed in Table 1.

Table 1. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
<i>Unpublished</i>			
NCT01053572 ^a	Evaluation of the Role of Steroids and 10% Hypertonic Sodium Chloride in Adhesiolysis in Post Lumbar Surgery Syndrome Patients: A Prospective, Randomized, Double-Blind, Equivalence, Controlled Trial of Percutaneous Lumbar Adhesiolysis	240	Jan 2014 (completed)
NCT01053273 ^a	Comparative Effectiveness of Percutaneous Adhesiolysis and Caudal Epidural Steroid Injections in Low Back and/or Lower Extremity Pain: A Randomized, Equivalence Trial	120	Jan 2014 (completed)

NCT: national clinical trial.

^a Denotes industry-sponsored or cosponsored trial.

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07/28/2003 Managed Care Advisory Council approval

07/14/2005 Medical Director review

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07/19/2005	Medical Policy Committee review. Format revision. Rationale/Source added. Policy statement unchanged.
07/25/2005	Managed Care Advisory Council approval
07/07/2006	Format revision, including addition of FDA and or other governmental regulatory approval and rationale/source. Coverage eligibility unchanged.
08/01/2007	Medical Director review
08/15/2007	Medical Policy Committee approval. Rationale updated. No change to coverage eligibility.
08/06/2009	Medical Policy Committee approval
08/26/2009	Medical Policy Implementation Committee approval. No change to coverage eligibility.
07/01/2010	Medical Policy Committee approval
07/21/2010	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/05/2010	Coding revision only
07/07/2011	Medical Policy Committee review
07/20/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/28/2012	Medical Policy Committee review
07/27/2012	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
03/05/2013	Coding revised
06/27/2013	Medical Policy Committee review
07/17/2013	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
07/10/2014	Medical Policy Committee review
07/16/2014	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
08/03/2015	Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section removed.
10/08/2015	Medical Policy Committee review
10/21/2015	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2016	Medical Policy Committee review

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10/19/2016 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

01/01/2017 Coding update: Removing ICD-9 Diagnosis Codes

07/06/2017 Medical Policy Committee review

07/19/2017 Medical Policy Implementation Committee approval. Coding update. Coverage eligibility unchanged.

11/07/2017 Coding update

07/05/2018 Medical Policy Committee review

07/11/2018 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

07/03/2019 Medical Policy Committee review

07/18/2019 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

07/02/2020 Medical Policy Committee review

07/08/2020 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

09/10/2020 Coding update

Next Scheduled Review Date: 07/2021

Coding

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Code Type	Code
CPT	62263, 62264, 62280, 62281, 62282, 64999
HCPCS	No codes
ICD-10 Diagnosis	G03.9, G96.12, M43.00-M43.19, M48.06-M48.07, M54.5, M99.23, M99.33, M99.43, M99.53, M99.63, M99.73 Delete code eff 10/1/2020: G96.19 Add codes eff 10/01/2020: G96.00-G96.09, G96.191, G96.198, G96.810-G96.819, G96.89

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:

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1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
3. Reference to federal regulations.

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