



**BlueCross BlueShield
of Alabama**

Name of Blue Advantage Policy:
Lysis of Epidural Adhesions

Policy #: 420
Category: Therapy

Latest Review Date: November 2020
Policy Grade: **Effective 11/19/2020:
Active policy but no
longer scheduled for
regular literature
reviews and updates.**

BACKGROUND:

Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
 - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
 - *Furnished in a setting appropriate to the patient's medical needs and condition;*
 - *Ordered and furnished by qualified personnel;*
 - *One that meets, but does not exceed, the patient's medical need; and*
 - *At least as beneficial as an existing and available medically appropriate alternative.*

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill **Original Medicare for covered services that are related to **clinical trials** that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

For dates of service on or after March 24, 2020:

Blue Advantage will treat **catheter-based techniques for lysis of epidural adhesions**, with or without endoscopic guidance, as a **non-covered benefit** and as **investigational**. Techniques used either alone or in combination include mechanical disruption with a catheter and/or injection of hypertonic solutions with corticosteroids, analgesics, or hyaluronidase.

Effective for dates of service February 26, 2018 through March 23, 2020, refer to LCD L36954.

Effective for dates of service prior to February 26, 2018.

Blue Advantage will treat **catheter-based techniques for lysis of epidural adhesions**, with or without endoscopic guidance, as a **non-covered benefit** and as **investigational**. Techniques used either alone or in combination include mechanical disruption with a catheter and/or injection of hypertonic solutions with corticosteroids, analgesics, or hyaluronidase.

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

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

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 syndrome." Both result from 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.

Both conditions 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, the pain is characterized as constant and burning. In some cases, the pain and disability are severe, leading to analgesic dependence and chronic invalidism.

Lysis of epidural adhesions, also called the Racz procedure, involves passage of a catheter (Racz catheter) endoscopically or percutaneously, using fluoroscopic guidance, with epidural injections of hypertonic saline in conjunction with corticosteroids and analgesics, has been investigated as a treatment option. Theoretically, the use of hypertonic saline results in a mechanical disruption of the adhesions. It 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. Prior to the use of endoscopy, adhesions can be identified as nonfilling lesions on fluoroscopy. Using endoscopy guidance, a flexible fiberoptic catheter is inserted into the sacral hiatus, providing 3-D visualization to steer the catheter toward the adhesions, to more 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 for the treatment of degenerative chronic low back pain, including spondylolisthesis, stenosis, and hernia associated with radiculopathy. Along with mechanical adhesiolysis, hyaluronidase, ciprofloxacin and ozone have been applied.

KEY POINTS:

This policy has been updated regularly with searches of the MEDLINE database. The most recent literature update was performed through August 20, 2020.

Summary of Evidence

The evidence for lysis of epidural adhesions in patients who have epidural adhesions includes randomized controlled trials (RCTs). Relevant outcomes include symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. Several RCTs report benefits for epidural lysis of adhesions compared with placebo treatment. Many of these trials are from the same center. The interpretation of these trials is limited by differences in patients, populations, and treatment protocol. The treatment for lysis of adhesions varies in the use of mechanical disruption, the type of lytic medications used, and the number of injections given. There is also a large effect seen in the placebo group, raising questions about whether some component of the placebo treatment may be therapeutic. Larger trials with standardized treatment protocols would be helpful in determining 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.

Practice Guidelines and Position Statements

American Society of Interventional Pain Physicians

The American Society of Interventional Pain Physicians updated their practice guidelines on the management of chronic spinal pain in 2013. The guideline states that “for lumbar percutaneous adhesiolysis, the evidence is fair in managing chronic low back and lower extremity pain secondary to post surgery syndrome and spinal stenosis.” Percutaneous adhesiolysis is recommended “after failure of conservative management of physical therapy, chiropractic, drug therapy, structured exercise program, and fluoroscopically directed epidural injections.” The guideline also states spinal epidural endoscopic adhesiolysis is not discussed since there is limited evidence and the procedure is rarely used. The studies cited in the guideline have been reviewed for this policy.

American Pain Society

The American Pain Society clinical practice guideline on Interventional Therapies, Surgery, and Interdisciplinary Rehabilitation for Low Back Pain, published in 2009, does not include a discussion or conclusion on adhesiolysis and 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.

KEY WORDS:

Epidural Neurolysis, Hypertonic Saline Injections, Injections, Epidural, Lysis of Epidural Adhesions, Neurolysis, Adhesiolysis, Racz procedure

APPROVED BY GOVERNING BODIES:

Not applicable

BENEFIT APPLICATION:

Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

CURRENT CODING:

CPT Codes:

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
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62264	;1 day only
64999	Unlisted procedure, nervous system

HCPCS Codes:

J7131	Hypertonic saline solution, 1ml
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REFERENCES:

1. Chopra P, Smith HS, Deer TR, et al. Role of adhesiolysis in the management of chronic spinal pain: A systematic review of effectiveness and complications. *Pain Physician* 2005; 8(1):87-100.
2. Chou R, Loeser JD, Owens DK et al. Interventional therapies, surgery, and interdisciplinary rehabilitation for low back pain: an evidence-based clinical practice guideline from the American Pain Society. *Spine (Phila Pa 1976)* 2009; 34(10):1066-1077.
3. Di Donato A, Fontana C, Pinto R et al. The effectiveness of endoscopic epidurolysis in treatment of degenerative chronic low back pain: a prospective analysis and follow-up at 48 months. *Acta Neurochir Suppl* 2011; 108:67-73.
4. Epter RS, Helm S 2nd, Hayek SM, et al. Systematic review of percutaneous adhesiolysis and management of chronic low back pain in post lumbar surgery syndrome. *Pain Physician* 2009; 12(2):361-378.
5. Gerdesmeyer L, Wagenpfeil S, Birkenmaier C et al. Percutaneous epidural lysis of adhesions in chronic lumbar radicular pain: a randomized, double-blind, placebo-controlled trial. *Pain Physician* 2013; 16(3):185-196.
6. Hayek SM, Helm S, Benyamin RM, et al. Effectiveness of spinal endoscopic adhesiolysis in post lumbar surgery syndrome: a systematic review. *Pain Physician* 2009; 12(2):419-435.
7. Heavner JE, Racz GB and Raj P. Percutaneous epidural neuroplasty: prospective evaluation of 0.9% NaCl versus 10% NaCl with or without hyaluronidase. *Reg Anesth Pain Med* 1999; 24(3):202-207.
8. Helm li S, Benyamin RM, Chopra P et al. Percutaneous adhesiolysis in the management of chronic low back pain in post lumbar surgery syndrome and spinal stenosis: a systematic review. *Pain Physician* 2012; 15(4):E435-462.
9. Helm S, Hayek SM, Colson J et al. Spinal endoscopic adhesiolysis in post lumbar surgery syndrome: an update of assessment of the evidence. *Pain Physician* 2013; 16(2 Suppl):SE125-150.
10. Manchikanti L, Abdi S, Atluri S et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. *Pain Physician* 2013; 16(2 Suppl):S49-283.

11. Manchikanti L, Boswell MV, Singe V, et al. American Society of Interventional Pain Physicians. Interventional techniques: Evidence-based practice guidelines in the management of chronic spinal pain. *Pain Physician* 2009; 12(1):699-802.
12. Manchikanti L, Cash KA, McManus CD, et al. The preliminary results of a comparative effectiveness evaluation of adhesiolysis and caudal epidural injections in managing chronic low back pain secondary to spinal stenosis: A randomized, equivalence controlled trial. *Pain Physician* 2009; 12(6):E341-354.
13. Manchikanti L, Malla Y, Wargo BW et al. A prospective evaluation of complications of 10,000 fluoroscopically directed epidural injections. *Pain Physician* 2012; 15(2):131-140.
14. Manchikanti L, Pakanati RR, Pampati V, et al. The value and safety of epidural endoscopic adhesiolysis. *Am J Anesthesiol* 2000; 27(5):275-279.
15. Manchikanti L, Pampati V, Bakhit CE, et al. Non-endoscopic and endoscopic adhesiolysis in post-lumbar laminectomy syndrome. *Pain Physician* 1999; 2(3):52-58.
16. Manchikanti L, Pampati V, Fellows B, et al. Role of one day epidural adhesiolysis in management of chronic low back pain: a randomized clinical trial. *Pain Physician*. Apr 2001; 4 (2):153-166.
17. Manchikanti L, Rivera JJ, Pampati V, et al. One day lumbar epidural adhesiolysis and hypertonic saline neurolysis in treatment of chronic low back pain: a randomized, double blind trial. *Pain Physician* 2004; 7(2):177-186.
18. Manchikanti L, Rivera JJ, Pampati V, et al. Spinal endoscopic adhesiolysis in the management of chronic low back pain: a preliminary report of a randomized, double-blind trial. *Pain Physician* 2003; 6(3):259-267.
19. Manchikanti L, Singh V, Cash KA, et al. A comparative effectiveness evaluation of percutaneous adhesiolysis and epidural steroid injections in managing lumbar post surgery syndrome: a randomized, equivalence controlled trial. *Pain Physician* 2009; 12 (6) E355-368.
20. Manchikanti L, Singh V, Cash KA et al. Assessment of effectiveness of percutaneous adhesiolysis and caudal epidural injections in managing post lumbar surgery syndrome: 2-year follow-up of a randomized, controlled trial. *J Pain Res* 2012; 5:597-608.
21. Manchikanti LM, Pampati V, Fellows B, et al. Role of one day epidural adhesiolysis in management of chronic low back pain: a randomized clinical trial. *Pain Physician* 2001; 4(2):153-166.
22. Racz GB, Heavner JE and Trescot A. Percutaneous lysis of epidural adhesions—evidence for safety and efficacy. *Pain Pract* 2008; 8(4):277-286.
23. Staal JB, de Bie RA, de Vet HC, et al. Injection therapy for subacute and chronic low back pain: An updated Cochrane review. *Spine (Phila Pa 1976)* 2009; 34(1):49-59.
24. Trescot AM, Chopra P, Abdi S, et al. Systematic review of effectiveness and complications of adhesiolysis in the management of chronic spinal pain: an update. *Pain Physician* 2007; 10(1):129-146.
25. Veihelmann A, Devens C, Trouillier H, et al. Epidural neuroplasty versus physiotherapy to relieve pain in patients with sciatica: a prospective randomized blinded clinical trial. *J Orthop Sci* 2006; 11(4):365-369.

26. Wagner KJ, Sprenger T, Pecho C, et al. [Risks and complications of epidural neurolysis – a review with case report.] *Anesthesiol Intensivmed Notfallmed Schmerzther* 2006; 41(4):213-222.

POLICY HISTORY:

Adopted for Blue Advantage, June 2010
Available for comment June 17-August 1, 2010
Medical Policy Group November 2010
Available for comment November 24, 2010 – January 10, 2011
Medical Policy Group, December 2011
Medical Policy Group, March 2012
Medical Policy Group, December 2012
Medical Policy Group December 2013
Medical Policy Group, January 2015
Medical Policy Group, December 2015
Medical Policy Group, November 2017
Medical Policy Group, February 2018
Medical Policy Group, April 2020: Reinstated effective March 24, 2020.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.