LOUISIANA BLUE

Lysis of Epidural Adhesions

Policy # 00037
Original Effective Date: 07/28/2003
Current Effective Date: 03/10/2025

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 lysis of epidural adhesions by any means, including but not limited to, use of hypertonic saline injections, mechanical catheter manipulation, hyaluronidase, whether done with or without steroids or analgesics, to be **investigational.***

Background/Overview

This document addresses lysis of epidural adhesions, which refers to the disruption of fibrous tissue in the epidural space of the spine. Epidural adhesions are similar to scar tissue and are most commonly observed following invasive procedures, such as spinal surgery, catheter placement, or injections. This procedure is also known as the RACZ procedure or epidural neurolysis. During the procedure, a special epidural catheter is inserted into the epidural space and lysis of the adhesions is conducted. Methods of lysis most commonly involve manipulation of the catheter to disrupt the adhesions, injection of a chemical lytic agent, such as hypertonic saline, with or without other agents, mechanical cutting, balloon dissection, and radiofrequency ablation.

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 conditions result from manipulation of the supporting structures of the spine and are related to inflammatory reactions that result in the entrapment of nerves within dense scar tissue. Arachnoiditis is most frequently seen in individuals who have undergone multiple surgical procedures. Lysis of epidural adhesions has been investigated as a treatment option.

Theoretically, the use of hypertonic saline in conjunction with corticosteroids and analgesics results in a disruption of epidural adhesions, thus relieving the pain caused by nerve entrapment. It may also function to reduce edema within previously scarred and inflamed nerves. Adhesions may also be disrupted by the manipulation of the catheter at the time of the injection or by catheter manipulation alone, without injected medication.

Multiple methods of adhesiolysis have been proposed, including the use of hypertonic saline, catheter manipulation, balloon dilation, and radiofrequency ablation.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to regulations, other plan medical policies, and accredited national guidelines.

In 2004, Manchikanti reported on a double-blind, placebo controlled trial that examined the role of mechanical epidural lysis of adhesions with or without additional hypertonic saline compared to placebo. A total of 75 participants were randomized to one of three groups: (1) a control group with catheterization without adhesiolysis followed by injection of local anesthetic, normal saline and steroid; (2) catheterization and adhesiolysis followed by injection of local anesthetic, normal saline and steroid; (3) adhesiolysis followed by injection of local anesthetic, hypertonic saline and steroids. Repeated treatments within the assigned group were permitted for up to 3 months. Beyond that time, unblinding was permitted if requested. After 12 months, all participants were unblinded. Outcome measures at 3, 6, and 12 months included Visual Analog Score (VAS) pain scale, Oswestry Disability Index (ODI), work status, opioid intake, range of motion exercises and psychological evaluation. At 3 months, when all participants remained blinded, the authors reported significant improvement in all outcome measures in the two active treatment groups compared to the control group. The treatment effect was quite strong, for example in both adhesiolysis groups, the mean VAS score dropped from 8.8 at the start of the study to between 4.7 and 4.8 at 3 months. Similarly, the ODI dropped from 37 to between 26 and 24. The proportion of participants using opioids dropped from 72% to 16%. This dramatic response in a small number of individuals raises questions about the reproducibility of results. In addition, while the participants and physical therapist were blinded to the treatment group, it is not clear if the treating physician was blinded. The protocol states that the treatment assigned was blinded to the "reviewing physician," but it is not clear who this physician is. For example, additional treatments were permitted "based on response," and it is unclear if this assessment was done in a blinded manner. The same group of investigators reported on an unblinded study of 45 participants who were randomly assigned to either a control group (n=15) who were treated conservatively, or to an active treatment group (n=30) treated with adhesiolysis. The participants were evaluated over 1.5 to 3 years. The treatment group reported increased improvement in terms of pain and function and other outcome measures compared to the control group. However, the small number of participants and lack of a placebo control group limits the interpretation of these results. It should also be noted that the majority of studies addressing adhesiolysis are authored by the same group of investigators, raising questions about the reproducibility of results (Manchikanti, 2001).

Veihelmann (2006) studied 99 participants with chronic low back pain who were randomly assigned to receive either physiotherapy (n=52) or epidural neurolysis (n=47) using ropivacaine, triamcinolone and 10% saline injected via catheter. Participants were assessed before treatment and

after 3, 6, and 12 months post treatment by a blinded investigator. This trial did not include a placebo control. After 3 months, the VAS score for back and leg pain was significantly reduced in the epidural neuroplasty group, and the need for pain medication was reduced in both groups. Furthermore, the VAS for back and leg pain as well as the Oswestry disability score were significantly reduced until 12 months after the procedure in contrast to the group that received conservative treatment. Although the researchers concluded that epidural neuroplasty results in significant alleviation of pain and functional disability in participants with chronic low back pain, they also acknowledged that further prospective randomized double-blind studies should be performed to prove the effectiveness of epidural neuroplasty in comparison to placebo and to open discectomy procedures.

Chun-jing et al (2012) reported on a single-center, double-blind population of 92 Chinese individuals with FBSS who received lysis of epidural adhesions. The participants were randomly divided into two groups, a control group of 46 participants and a treatment group of 46 participants. The control group received an epidural injection of dexamethasone, while the treatment group received lysis of epidural adhesions followed by epidural injection of dexamethasone. Participants were evaluated prior to the procedure, at 7 days, 1 month, and 6 months following the procedure. All participants completed VAS questionnaires. VAS score for the control group before operation was 7.03, 5.47 at 7 days, 6.00 at 1 month and 6.21 at 6 months. VAS for the treatment group before operation was 6.95, 3.50 at 7 days, 3.55 at 1 month and 3.71 at 6 months. Six participants in the treatment group failed lysis and did not show any change in VAS scores. Sixteen of the 92 participants were lost to follow-up. The authors concluded that the decrease in VAS scores in the control group may have been attributed to the use of dexamethasone. Although the VAS scores for the treatment group were lower than the control group, this is a small group of participants and there was no long-term follow-up.

Manchikanti and colleagues (2012) reported on the 2-year outcomes of a randomized, controlled trial in which 120 participants were randomly assigned to either the control group which consisted of caudal epidural injections with catheterization (n=60) or the intervention group (n=60) which consisted of percutaneous adhesiolysis with lidocaine, hypertonic sodium chloride and betamethasone. The participants were post lumbar surgery at least 6 months prior to enrollment and all had failed conservative management. The outcome measures used were Numeric Rating Scale (NRS), the ODI 2.0, opioid use and employment status. Assessments were carried out at 3, 6, 12, 18, and 24 months post-treatment. At 2 years, 8 participants in the control group were available for follow-up and 52 participants had been unblinded, compared to the intervention group in which 54 participants were available for follow-up and 4 participants were unblinded. Pain relief and improvement in functional status were noted in 70% of the participants in the intervention group at the end of 1 year and 82% at the end of 2 years, compared to 5% at the end of years 1 and 2 in the control group. There was no change in employment status. Opioid use was decreased from the baseline, but there were no significant differences between the groups. The authors acknowledged that, given the subjective outcome of pain relief, an equivalence study with no placebo/sham control

is difficult to interpret; secondly, there was a large control group dropout rate (n=43 in control group; n=3 in intervention group) at 12 months.

Rapcan (2017) published a randomized, multicenter, double-blind, parallel pilot study comparing the efficacy of drugs (hyaluronidase and corticosteroid DEPO-Medrol) administered into the epidural space during epiduroscopy and mechanical adhesiolysis. Before epiduroscopy, 48 participants were randomized into either Group A (mechanical adhesiolysis) or Group B (hyaluronidase and corticosteroid DEPO-Medrol). At the 6-month and 12-month double-blinded postoperative examinations, primary outcomes, which were pain intensity spreading in the back and legs and evaluation of the Oswestry Disability Index (ODI), were assessed. The authors found that the ODI score significantly improved in both groups at the 6-month appointment ($p<0.05$), but returned to baseline at the 12-month appointment for both groups. Also, results were similar with back and leg pain in that they were significantly improved in both groups at the 6-month appointment ($p<0.05$), but the improvement diminished by the 12-month appointment for Group A back pain and leg pain for both groups ($p>0.05$). Based on these results, mechanical adhesiolysis and adhesiolysis with corticosteroid and hyaluronidase administration both do not have long-term benefits.

Gerdesmeyer (2021) published the 10-year follow-up results of a randomized, sham-controlled trial assessing the efficacy of lumbar epidural lysis of adhesions in individuals with chronic radicular pain. The initial study involved 90 participants who were randomly assigned to receive percutaneous epidural lysis of adhesions with bupivacaine, hyaluronidase, and hypertonic saline or placebo with concealed allocation. The primary outcomes were a mean change of the ODI scores and VAS at 1 and 10 years after intervention. A 50% improvement in ODI and VAS scores was considered clinically relevant. At 1 year, 34% of the placebo group and 90% of the intervention group met the benchmark for clinically relevant improvement in ODI scores ($p<0.01$). Regarding VAS scores, 69% of the placebo group and 93% of the intervention group met the clinically relevant benchmark ($p<0.032$). Both groups had sustained clinically relevant improvement 10 years after the intervention. The statistical difference of the ODI and VAS scores between the treatment and control groups remained significant at the 10-year follow-up (ODI, $p=0.001$; VAS, $p=0.001$). However, there was a large loss to follow-up in both groups. Of the 44 participants initially randomized to the placebo group, 42 completed the 3-month assessments, 26 completed the 12-month, and only 23 completed the 10-year follow-up. Of the 46 randomized to the intervention group, 46 completed the 3-month assessments, 31 completed the 12-month assessments, and 29 completed the 10-year follow-up. The study is limited by several confounding elements including a large variety of unanalyzed noninvasive treatments across 10 years, a lack of participant recall of the intervention, changes in biometric status, changes in pain tolerance, and a large loss to follow-up.

In addition to these RCTs, multiple cohort and case series studies have been published describing the outcomes of lysis of epidural adhesion procedures (Cho, 2019; Donato, 2011; Funao, 2022; Gazzeri, 2023; Hong Park, 2017; Kim, 2023; Kose, 2023; Pereira, 2016; Takeshima, 2009; Vigneri, 2021). These studies include a mix of prospective and retrospective methodologies, widely varying

populations sizes, follow-up periods, and use a variety of lysis methods; and all lack use of randomization and blinding. While most report favorable outcomes, due to the lack of rigorous methodologies, results do not permit reasonable conclusions concerning the effect of the lysis of epidural adhesion procedures on health outcomes.

Society Recommendations
The American Society of Interventional Pain Physicians (ASIPP) published a guideline addressing epidural interventions in the management of chronic spinal pain in 2021 (Manchikanti, 2021). That document included the following statements regarding the use of percutaneous adhesiolysis:

- The evidence for percutaneous adhesiolysis in managing disc herniation based on one high-quality, placebo-controlled RCT is Level II with moderate to strong recommendation for long-term improvement in patients nonresponsive to conservative management and fluoroscopically guided epidural injections
- The evidence for percutaneous adhesiolysis in lumbar stenosis based on relevant, moderate to high quality RCTs, observational studies, and systematic reviews is Level II with moderate to strong recommendation for long-term improvement after failure of conservative management and fluoroscopically guided epidural injections.
- For percutaneous adhesiolysis, based on multiple moderate to high-quality RCTs and systematic reviews, the evidence is Level I with strong recommendation for long-term improvement after failure of conservative management and fluoroscopically guided epidural injections.

These recommendations are based on clinical trial data from the RCTs mentioned above, as well as several review and metanalysis documents that re-evaluated the data from those studies. As noted above, those studies included significant methodological limitations that hinder their utility and generalizability.

Summary
Overall, there is insufficient credible evidence demonstrating that procedures for the lysis of epidural adhesions result in an improvement in net health outcomes. Well designed and conducted trials with long-term follow-up are needed to assess the clinical utility of this treatment, as well as determine optimal methods of lysis, and establish patient selection criteria.

Supplemental Information/Definitions

Definitions
Arachnoiditis: Inflammation of the arachnoid membrane often with involvement of the subjacent subarachnoid space.

Endoscope: A usually highly flexible viewing instrument with capabilities of diagnostic (biopsy) or even therapeutic functions through special channels.

Endoscopy: The visual inspection of any cavity of the body by means of an endoscope.

Neurolysis: Destruction of nerve tissue; freeing of a nerve from inflammatory adhesions.

Radiculopathy: Any disease of the spinal nerve roots and spinal nerves. Radiculopathy is characterized by pain which seems to radiate from the spine to extend outward to cause symptoms away from the source of the spinal nerve root irritation. Causes of radiculopathy include deformities of the discs between the building blocks of the spine (the vertebrae).

References

Peer Reviewed Publications:

1. Cho PG, Ji GY, Yoon YS, et al. Clinical effectiveness of percutaneous epidural neuroplasty according to the type of single-level lumbar disc herniation: a 12-month follow-up study. J Korean Neurosurg Soc. 2019; 62(6):681-690.
2. Chopra P, Smith HS, Deer TR, Bowman RC. Role of adhesiolysis in the management of chronic spinal pain: A systematic review of effectiveness and complications. Pain Physician. 2005; 8:87-100.
3. Chun-jing H, Hao-xiong N, Jia-xiang N. The application of percutaneous lysis of epidural adhesions in patients with failed back surgery syndrome. Acta Cir Bras. 2012; 27(4):357-362.
4. 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.
5. Funao H, Yokosuka K, Ukai J, et al. Efficacy of minimally invasive trans-sacral canal plasty between patients with and without failed back surgery syndrome. Medicina (Kaunas). 2022; 58(2):251.
6. Gazzeri R, Tribuzi S, Leoni MLG, et al. Evaluation of lumbar adhesiolysis using a radiofrequency catheter during epiduroscopy in the treatment of failed back surgery syndrome (FBSS). Surg Technol Int. 2023; 43:sti43/1714.
7. Gerdesmeyer L, Noe C, Prehn-Kristensen A, et al. Long-term efficacy of percutaneous epidural neurolysis of adhesions in chronic lumbar radicular pain: 10 year follow-up of a randomized controlled trial. Pain Physician. 2021; 24(5):359-367.
8. 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.
9. Geudeke MW, Krediet AC, Bilecen S, et al. Effectiveness of epiduroscopy for patients with failed back surgery syndrome: a systematic review and meta-analysis. Pain Pract. 2021; 21(4):468-481.
10. 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.

11. Hong Park C, Ho Lee S. Epidurographic findings following percutaneous epidural adhesiolysis failed to correlate with level of pain reduction in patients with lumbar spinal stenosis. Pain Med. 2017; 18(5):842-845.
12. Kim HJ, Cho YB, Bae J, Kim SH. Relationship between time elapsed since pain onset and efficacy of pain relief in patients undergoing lumbar percutaneous epidural adhesiolysis. Yonsei Med J. 2023; 64(7):448-454.
13. Kose HC, Akkaya OT. Predictive factors associated with successful response to percutaneous adhesiolysis in chronic lumbar radicular pain. J Clin Med. 2023; 12(19):6337.
14. 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. 2009a; 12(6):E341-E354.
15. Manchikanti L, Cash KA, McManus CD, Pampati V. Assessment of effectiveness of percutaneous adhesiolysis in managing chronic low back pain secondary to lumbar central spinal canal stenosis. Int J Med Sci. 2013; 10(1):50-59.
16. Manchikanti L, Knezevic NN, Sanapati MR, et al. Effectiveness of percutaneous adhesiolysis in managing chronic central lumbar spinal stenosis: a systematic review and meta-analysis. Pain Physician. 2019; 22(6):E523-E550.
17. Manchikanti L, Manchikanti KN, Gharibo CG, Kaye AD. Efficacy of percutaneous adhesiolysis in the treatment of lumbar post surgery syndrome. Anesth Pain Med. 2016; 6(2):e26172.
18. 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. 2001; 4(2):153-166.
19. 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.
20. 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. 2009b; 12(6):E355-E368.
21. Manchikanti L, Singh V, Cash KA, Pampati V. 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.
22. Pereira P, Severo M, Monteiro P, et al. Results of lumbar endoscopic adhesiolysis using a radiofrequency catheter in patients with postoperative fibrosis and persistent or recurrent symptoms after discectomy. Pain Pract. 2016; 16(1):67-79.
23. Racz GB, Heavner JE, Trescot A. Percutaneous lysis of epidural adhesions--evidence for safety and efficacy. Pain Pract. 2008; 8(4):277-286.
24. Rapcan R, Kocan L, Mláka J. A randomized, multicenter, double-blind, parallel pilot study assessing the effect of mechanical adhesiolysis vs adhesiolysis with corticosteroid and hyaluronidase administration into the epidural space during epiduroscopy. Pain Med. 2018; 19(7):1436-1444.

25. Takeshima N, Miyakawa H, Okuda K, et al. Evaluation of the therapeutic results of epiduroscopic adhesiolysis for failed back surgery syndrome. Br J Anaesth. 2009; 102(3):400-407.
26. Trescot A, 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.
27. 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.
28. Vigneri S, Sindaco G, La Grua M, et al. Long-term inhibition of soleus h-reflex with epidural adhesiolysis and pulsed radiofrequency in lumbosacral neuropathic pain. Pain Pract. 2021; 21(3):277-284.

Government Agency, Medical Society, and Other Authoritative Publications:

1. Manchikanti L, Knezevic NN, Navani A, et al. Epidural interventions in the management of chronic spinal pain: American Society of Interventional Pain Physicians (ASIPP) comprehensive evidence-based guidelines. Pain Physician. 2021; 24(S1):S27-S208.

Policy History

Original Effective Date: 07/28/2003
Current Effective Date: 03/10/2025

07/28/2003	Managed Care Advisory Council approval
07/14/2005	Medical Director review
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
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
02/04/2021	Medical Policy Committee review
02/10/2021	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
02/03/2022	Medical Policy Committee review
02/09/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Lysis of Epidural Adhesions

Policy # 00037
Original Effective Date: 07/28/2003
Current Effective Date: 03/10/2025

02/02/2023	Medical Policy Committee review
02/08/2023	Medical Policy Implementation Committee approval Coverage eligibility unchanged.
03/10/2023	Coding update
02/01/2024	Medical Policy Committee review
02/14/2024	Medical Policy Implementation Committee approval. Extensive revisions made to the policy. Coverage intent is unchanged.
02/06/2025	Medical Policy Committee review
02/12/2025	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 02/2026

Coding

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2024 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	62263, 62264, 64999
HCPCS	No codes
ICD-10 Diagnosis	All related diagnoses

*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:
    1. Consultation with 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.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.