Lysis of Epidural Adhesions

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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 for injection of hypertonic saline with or without other medications or manipulation of the catheter alone. Additional lysis methods have been proposed, such as 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 with epidural injections of hypertonic saline, in conjunction with steroids, and analgesics or hyaluronidase has been investigated as a treatment option. Theoretically, the use of hypertonic saline results in a mechanical disruption of the adhesions while some advocates contend adhesiolysis can be obtained by the manipulation of the catheter with or without the injection of hypertonic saline. The hypertonic saline may also function to reduce edema within previously

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scarred or inflamed nerves. Hyaluronidase may be added to the injectate in an attempt to further the penetration of drugs into the scar tissue.

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 federal regulations, other plan medical policies, and accredited national guidelines.

Theoretically, the use of hypertonic saline in conjunction with corticosteroids and analgesics results in a disruption of the 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.

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

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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.

Takeshima and colleagues (2009) performed epidural adhesiolysis on 28 individuals with failed back surgery syndrome (FBSS), to examine whether the location of the adhesions was responsible for successful pain relief. The authors found that in those where only the epidural space was separated by adhesiolysis, there was a significant improvement in the Roland–Morris disability questionnaire (RDQ) score until 12 weeks after adhesiolysis, but the score gradually returned to the preoperative value thereafter. Among those where the nerve root responsible for radicular pain was separated, there was a long-term improvement in the RDQ and the ODI. Among participants where both the

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epidural space and the nerve root responsible for pain were separated, there was a 12-week improvement in the RDQ score and 24-week improvements in the ODI scores. The authors acknowledged the limitations of this study were size, treatment comparison and blinding. Larger, well designed controlled studies are necessary to establish the clinical utility of epiduroscopic adhesiolysis.

Donato and colleagues (2011) reported a 48-month follow-up from a prospective case series of 234 individuals with chronic low back pain due to FBSS, spondylolisthesis, stenosis or hernia. In addition to mechanical removal of adherences, targeted ozone, hyaluronidase and ciprofloxacin were applied. Efficacy was prospectively evaluated by an independent investigator at 1 week and 3, 6, 12, 24, 36, and 48 months. Significant improvements in VAS and ODI scores were reported throughout the 48-month follow-up. Adverse events included 32 individuals (13.7%) having sacral pain lasting at least 2 weeks and 13 individuals (5.5%) experiencing a non-painful paresthesia and who subsequently underwent surgical intervention. Although positive outcomes were reported, the study was limited by the lack of a control group and a large number of participants lost to follow-up at 48 months.

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

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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.

In 2016, Pereira and others 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

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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.

Hong Park and Ho Lee (2017) investigated the correlation between level of pain reduction and epidurographic findings in subjects with lumbar spinal stenosis. In this prospective study, 78 subjects underwent percutaneous adhesiolysis procedures and had postprocedural follow-up appointments at 2 weeks, 1 month, and 3 months. The VAS score assessment was used to obtain outcome measures at all follow-up appointments. The investigators found that "no significant correlation between postprocedural VAS score and status of filling defects (yes or no) was evident during the three-month follow-up period" (2 weeks: $p=0.44$; 1 month: $p=0.83$; 3 months: $p=0.75$) (Hong Park, 2017).

Also in 2017, Rapcan and colleagues 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 subjects 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.

A retrospective analysis that evaluated the effect of the type of lumbar disc herniation (LDH) on percutaneous epidural neuroplasty (PEN) outcomes, and the effectiveness of PEN in individuals with single-level LDH was published in 2019 by Cho and colleagues. A total of 430 consecutive individuals with single-level LDH who underwent PEN were included in the study. Categories for LDH pretreatment type were bulging, protrusion, extrusion, and sequestration. The evaluators found the mean preoperative VAS score for back pain to be 6.90 and for leg pain to be 4.23. During the

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follow-up period, there were decreases in back pain and leg pain VAS scores after PEN as follows: 2.25 and 1.45, respectively, at 1 month; 2.61 and 1.68, respectively, at 3 months; 2.28 and 1.48, respectively, at 6 months; and 2.88 and 1.48, respectively, at 12 months ($p<0.001$). While the decrease in VAS scores for leg pain was significantly greater in the extrusion and sequestration categories when compared to the other groups ($p<0.05$), there were no other significant differences noted between the LDH type categories. "More than 70% patients exhibited good or excellent 12-month outcomes according to Odom's criteria [and] subsequent surgery was required for 59 patients (13.7%)" (Cho, 2019). The results showed that PEN is a potential treatment for back and leg pain caused by single-level LDH and that LDH type does not have an effect on PEN outcomes; however, there are several limitations to this study including retrospective design, lack of control group, and uneven distribution of individuals according to type of LDH.

In 2019, Manchikanti and colleagues released the results of a systematic review and meta-analysis on the effectiveness of percutaneous adhesiolysis in managing chronic central lumbar spinal stenosis. The systematic review yielded 2 randomized controlled trials (RCT), 2 prospective studies, and 2 retrospective studies with a total of 333 individuals. "Conventional-arm analysis was not feasible due to heterogeneity among the only 2 RCTs available. Consequently, single-arm meta-analysis was performed" (Manchikanti, 2019). The single-arm meta-analysis did not include all studies from the systematic review in the analysis of each follow-up period. Five studies with 255 individuals were included in the 3-month analysis of pain and functionality. At 3 months, results showed an improvement in the NRS pain scores for pain after percutaneous adhesiolysis, on average 3.801 ($p<0.001$) and an improvement in the ODI functionality scores after percutaneous adhesiolysis, on average 15.039 (on 0-50 scale) ($p<0.001$). Four studies with 225 individuals were included in the 6-month analysis of pain and functionality. At 6 months, results showed an improvement in the NRS pain scores for pain after percutaneous adhesiolysis, on average 3.707 ($p<0.001$) and an improvement in the ODI functionality scores after percutaneous adhesiolysis, on average 14.854 (on 0-50 scale) ($p<0.001$). Three studies with 181 individuals were included in the 12-month analysis of pain and functionality. At 12 months, results showed an improvement in the NRS pain scores for back pain after percutaneous adhesiolysis, on average 3.847 ($p<0.001$) and an improvement in the ODI functionality scores after percutaneous adhesiolysis, on average 15.394 (on 0-50 scale) ($p<0.001$). The authors graded the evidence a Level II/Moderate: "Evidence obtained from at least one relevant high quality randomized controlled trial or multiple relevant moderate or low quality randomized controlled trials" (Manchikanti, 2019). While there are positive results, this single-arm meta-analysis has several limitations, such as the small number of included studies in

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each analysis, and the same primary author for the meta-analysis, one of the included studies, and the tool used to grade the evidence.

Gerdesmeyer and colleagues (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 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.

Geudeke and colleagues (2021) published a systematic review with meta-analysis evaluating the effectiveness of epiduroscopy in individuals with failed back surgery syndrome (FBSS). The review included 9 studies, 2 of which were RCTs, involving 392 participants. The average score on the VAS assessment for pain was 7.6 at baseline, 4.5 at 6 months, and 4.3 at 12 months. The ODI average was 61.7% at baseline, 42.8% at 6 months, and 46.9% at 12 months. An average of 49% of participants experienced significant pain relief at 6 months, and 37% at 12 months. The pooled VAS mean difference was 3.4 (95% confidence interval [CI], 2.6 to 4.1) and 2.8 (95% CI, 1.6 to 4.0), and pooled ODI mean difference of 19.4% (95% CI, 12.5% to 26.4%) and 19.8% (95% CI, 13.8 to 25.9%) at 6 and 12 months, respectively. The evidence suggests that mechanical adhesiolysis may be beneficial for some individuals with FBSS. However, there were several limitations of the analysis including few studies objectively comparing epiduroscopy with other interventions, lack of

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standardized criteria for diagnosis of FBSS, and possible confounding interventions during follow-up. The authors rated the quality of evidence as moderate and the corresponding level of recommendation as weak.

Vigneri and colleagues (2021) published the results of a prospective study evaluating the effects of electrocatheter-mediated epidural adhesiolysis and pulsed radiofrequency (PRF) on sural nerve conduction and Hoffman reflex (H-reflex) in individuals with lumbosacral L5 to S1 radiculopathies. The authors also intended to compare the obtained neurophysiological data with clinical outcomes after treatment. The study involved 17 individuals that underwent 2 cycles of 240 seconds high-voltage PRF combined with epidural adhesiolysis. Neurophysiological testing was completed 5 minutes before and after PRF in each participant. Pain intensity was assessed by 0 to 10 numbering rating scale (NRS) and neuropathic features with the Douleur Neuropathique 4 Questions (DN4) before the intervention and at 1-month follow-up. At follow-up, pain reduction on NRS of ≥ 30% compared to baseline was considered a successful response to treatment. After 1 month, a significant reduction in NRS and DN4 scores was observed in 53% of participants reporting pain improvement of ≥ 30% over baseline (p=0.02). The H/M ratio (the ratio of maximum H-reflex to maximum M response) decreased in the treated limb immediately following the treatment (p=0.01) and at follow-up (p=0.04). A direct correlation was observed between H/M ratio and NRS score at follow-up in the treated limb (p=0.04). The results indicate epidural adhesiolysis combined with PRF is a promising strategy for the management of lumbosacral radiculopathies in this group of individuals. However, there were several limitations including the lack of blinding, control comparison, limited sample size, and the use of the DN4 questionnaire which has not been validated for radicular pain.

Funao (2022) published the results of a retrospective cohort study involving 271 subjects with chronic low back and leg pain as a result of lumbar spinal disorders who underwent minimally invasive adhesiolysis using what the authors refer to as “trans-sacral canal plasty (TSCP)”. As described by the authors, TSCP appears to be a standard adhesiolysis procedure followed by epidural administration of steroid and lidocaine/bupivicaine. All subjects had at least 6 months of follow-up post procedure. No prior history of lumbar spinal surgery was noted in 191 subjects and 80 had failed prior lumbar procedures. The authors reported subjective VAS pain scores for low back pain at baseline, immediately postoperatively and at 1, 3, and 6 months. While scores for low back pain and leg pain were significantly decreased from baseline in both the prior surgery and surgery naïve groups (p<0.01), scores for leg pain at 3 months and 6 months were significantly higher in the prior surgery group (p<0.05). Greater than 50% reduction in low back pain VAS score at 3 months was

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reported for 37.2% of surgery naïve subjects and in 31.3% of subjects with prior failed surgery. Similarly, a more than 50% reduction in leg pain VAS score for leg pain at 3 months was reported in 46.6% of surgery naïve subjects and in 32.5% of subjects with failed surgery. No significant differences between the groups were reported for low back pain, but leg pain remained significant in the subjects with prior failed surgery ($p<0.05$). There were three catheter breakages and one dural tear reported. Progression to definitive surgical procedures to treat residual low back or leg pain or neurological deterioration was reported in 32.1% of all subjects within the 6-month follow-up time point. The authors concluded that TSCP significantly reduced both VAS scores for low back and leg pain in subjects with and without prior surgical procedures. However, the weak methodology of this trial, including its retrospective nature, lack of objective measures, blinding, and control group, weakens the generalizability of these results.

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 flaws that hinder their utility and generalizability. Combining flawed data in a larger analysis does not mitigate the concerns regarding those flaws.

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Overall, evidence addressing procedures for the lysis of epidural adhesions is weak. Rigorously designed and conducted trials with long-term follow-up are needed to better understand the clinical utility of this treatment.

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).

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Lysis of Epidural Adhesions

Policy # 00037
Original Effective Date: 07/28/2003
Current Effective Date: 03/11/2024

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: 03/11/2024

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

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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

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02/09/2022	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
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.

Next Scheduled Review Date: 02/2025

Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 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.

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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 Delete codes effective 04/01/2023: 62280, 62281, 62282
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.

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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.

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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.

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