2.01.85	Neural Therapy		
Original Policy Date:	March 1, 2016	Effective Date:	February 1, 2024
Section:	2.0 Medicine	Page:	Page 1 of 10

Policy Statement

I. Neural therapy is considered **investigational** for all indications.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Neural therapy should be distinguished from the use of peripherally injected anesthetic agents for nerve blocks or local anesthesia. The site of the injection for neural therapy may be located far from the source of the pain or injury. The length of treatment can vary from 1 session to a series of sessions over a period of weeks or months.

Coding

There are no specific HCPCS codes for these local anesthetics when injected in this fashion (there is a code for IV lidocaine). The procedure would be reported using CPT codes for therapeutic injection such as:

- 20550: Injection(s); single tendon sheath, or ligament, aponeurosis (e.g., plantar "fascia")
- 20551: Injection(s); single tendon origin/insertion
- 20552: Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s)
- 20553: Injection(s); single or multiple trigger point(s), 3 or more muscles
- 64400-64450: Code range for injection, anesthetic agent into nerves
- 64479-64484: Code range for injection, anesthetic agent and/or steroid, transforaminal epidural, with imaging guidance by spinal region
- 64505-64530: Code range for injection, anesthetic agent into autonomic nerves/ganglia

Description

Neural therapy involves the injection of a local anesthetic such as procaine or lidocaine into various tissues such as scars, trigger points, acupuncture points, tendon and ligament insertions, peripheral nerves, autonomic ganglia, the epidural space, and other tissues to treat chronic pain. Neural therapy has been proposed for other chronic illness syndromes such as allergies, infertility, tinnitus, multiple sclerosis, depression, and chronic bowel problems. When the anesthetic agent is injected into traditional acupuncture points, this treatment may be called neural acupuncture.

Related Policies

- Autonomic Nervous System Testing
- Prolotherapy

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

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Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

Neural therapy is a procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

Rationale

Background

The practice of neural therapy is based on the belief that energy flows freely through the body. It is proposed that injury, disease, malnutrition, stress, and scar tissue disrupt this flow, creating disturbances in the electrochemical function of tissues and energy imbalances called "interference fields." Injection of a local anesthetic is believed to re-establish the normal resting potential of nerves and flow of energy. Alternative theories include fascial continuity, the ground (matrix) system, and the lymphatic system.¹

There is a strong focus on treatment of the autonomic nervous system, and injections may be given at a location other than the source of the pain or location of an injury. Neural therapy is promoted mainly to relieve chronic pain. It has also been proposed to be helpful for allergies, hay fever, headaches, arthritis, asthma, hormone imbalances, libido, infertility, tinnitus, chronic bowel problems, sports or muscle injuries, gallbladder, heart, kidney, or liver disease, dizziness, depression, menstrual cramps, and skin and circulation problems.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Promotion of greater diversity and inclusion in clinical research of historically marginalized groups (e.g., People of Color [African-American, Asian, Black, Latino and Native American]; LGBTQIA (Lesbian, Gay, Bisexual, Transgender, Queer, Intersex, Asexual); Women; and People with Disabilities [Physical and Invisible]) allows policy populations to be more reflective of and findings more applicable to our diverse members. While we also strive to use inclusive language related to these

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groups in our policies, use of gender-specific nouns (e.g., women, men, sisters, etc.) will continue when reflective of language used in publications describing study populations.

Clinical Context and Therapy Purpose

The purpose of neural therapy in individuals with chronic pain is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals who have chronic pain or other chronic illnesses (e.g., allergies, infertility, tinnitus, multiple sclerosis, depression, and chronic bowel problems).

Interventions

The therapy being considered is injection of local anesthetics (e.g., procaine, lidocaine) for neural therapy.

Comparators

The comparators currently being used include standard medical management, injection of other substances such as normal saline or corticosteroids, or exercise-based modalities.

Outcomes

The outcomes of interest are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

Boluk Senlikci et al (2021) conducted a single-center, randomized, nonblinded, controlled trial in Turkey that compared neural therapy (20 mL of local anaesthetic, 1:100 mixture of 10 mg/mL procaine) plus a hand rest and thumb spica splint (n=20) or a hand rest and thumb spica splint alone (n=19) in patients with De Quervain tenosynovitis.^{2,} Although the Duruoz Hand Index (DHI) score was lower in the neural therapy group at 1 month (8.94 vs 16.61; p=.009), scores were similar at 12 months (8.83 vs 12.66; p=.252). Key limitations of this trial include that the important outcomes of quality of life and function were not addressed and that the study was unblinded.

Altinbilek et al (2019) conducted a multicenter, RCT that compared neural therapy (with lidocaine 0.5%) plus exercise (n=42) to exercise alone (n=30) in patients with fibromyalgia.^{3,} At 6 weeks, the visual analogue pain scale (p=.038) and Beck Depression Scale (p=.049) scores were significantly reduced with neural therapy compared to the control group. At 10 weeks, there were no significant differences among groups in pain, quality of life, functional status, or depression or anxiety scores. AnRCT by Nazlikul et al (2018) compared the efficacy of neural therapy (6 sessions, n=51) plus stretching to stretching alone (n=51) in patients with low back pain due to piriformis syndrome.^{4,} At the end of treatment, visual analogue pain scale (6.3 \pm 7.5 vs 37.2 \pm 10.4; p<.01) and Oswestry

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Disability Index (range 0 to 100; 15.2 ± 8.5 vs 32.2 ± 11.9 ; p<.01) scores were significantly improved with neural therapy compared to stretching alone.

Montenegro et al (2015) conducted a RCT to compare the effect of trigger point injection (with lidocaine 0.5%, once weekly for 4 weeks) to ischemic compression physical therapy (PT) followed by transcutaneous electrical nerve stimulation (given 4 times weekly for 4 weeks) in 30 women with chronic pelvic pain and abdominal wall trigger points. 5 , The trial was stopped early after results showed superiority in the trigger point injection group. Clinical response (defined as visual analogue pain scale reduction of at least 50% or significant subjective improvement in daily life activities) was significantly better in the trigger point injection group compared to the PT group at 1 week after treatment (80% vs 40%; p=.018), 4 weeks after treatment (80% vs 40%; p=.018), and 12 weeks after treatment (73.3% vs 13.3%; p=0.00006). Differences in visual analogue pain scores were significant between groups at weeks 4 and 12 (both p<.01).

Nonrandomized Trials

A retrospective cohort study by Batur et al (2020) compared the effect of neural therapy (with lidocaine 1%) and PT among 60 women with fibromyalgia, both in combination with a home exercise regimen. Efficacy after 4 weeks was evaluated with a visual analogue pain scale, Short Form 36 (SF-36) scores, and Fibromyalgia Impact Questionnaire (range 0 to 100) scores. Visual analogue scale (mean 3.70 ± 2.21 versus 5.10 ± 1.68 ; p=0.003) and Fibromyalgia Impact Questionnaire (mean 40.73 ± 18.39 versus 46.00 ± 15.97 ; p=0.008) scores were significantly reduced with neural therapy compared to PT. Several SF-36 subscores were significantly improved with neural therapy compared to PT including physical functioning (p=0.046), energy/fatigue (p=0.005), emotional well-being (p=0.02), bodily pain (p=0.047), and general health (p=0.013).

Egli et al (2015) reported on a series of 280 patients with chronic severe pain who had failed conventional medical measures.^{7,} The most common reason for referral to the academic center in Europe was back pain, and more than two-thirds of patients had undergone PT, osteopathy, or chirotherapy. After an average of 9.2 treatments (range, 1 to 40) in the first year, 126 patients reported that they were considerably better and 41 reported being pain-free. Of the 193 patients who were taking pain medications at the start of treatment, three-quarters had reduced pain medication or were taking no pain medication after 1 year.

A nonrandomized comparative study by Atalay et al (2013) compared neural therapy (n=33) with PT (n=27) for the treatment of chronic low back pain.^{8,} The average duration of symptoms before treatment was 13.78 months. Patients who had not previously been treated with PT were assigned to the PT group, and patients who had previously failed PT were assigned to the neural therapy group. PT consisted of exercises, hot pack, ultrasound, and transcutaneous electrical nerve stimulation over 15 sessions. Neural therapy consisted of anesthetic injection into scars, trigger points, and acupuncture points over 5 sessions. Outcome measurements included the visual analog score for pain, the Roland-Morris Disability Questionnaire for disability, the Nottingham Health Profile for quality of life, and the Hospital Anxiety Depression Scale for depression, anxiety, and quality of life. The neural therapy group exhibited greater disability and worse quality of life at baseline. Both groups improved over time, and there was greater improvement in the neural therapy group on some of the outcome measures. Interpretation of this study is limited due to lack of randomized treatment assignment, comparability between groups at baseline, and a placebo control.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US

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representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Neurology

In 2014, the American Academy of Neurology guideline on complimentary and alternative therapies for multiple sclerosis stated that there is insufficient evidence to support or refute the efficacy of neural therapy. Due to inadequate data, the guideline classifies neural therapy treatment as 'unproven' for this indication. The evidence reviewed was limited to a single Class III study (controlled study with independent outcome assessment) that evaluated the effect of neural therapy on disability in patients with all forms of multiple sclerosis. Among 61 patients with various forms of multiple sclerosis, 69% had improved Expanded Disability Status Scores which were sustained in 29% of patients during long-term follow-up (2 to 3.5 years). The 2014 guideline was reaffirmed in February 2023.

American College of Obstetricians and Gynecologists

In 2020, the American College of Obstetricians and Gynecologists practice bulletin on chronic pelvic pain recommends trigger point injections (alone or in combination with other treatments) for improving pain and function in patients with myofascial chronic pelvic pain (Level A recommendation – based on good and consistent scientific evidence). In particular, trigger point injections may be effective for pelvic floor muscle spasm that is refractory to pelvic floor PT and medications. Injection at trigger points in the abdominal wall may be more effective than ischemic compression PT. Examples of medications that can be used for this type of injection include saline, anesthetics, steroids, or opioids; no medication is specifically recommended for or against and the guideline authors speculate that needle injection may itself account for some of the therapeutic effect. Symptom relief may occur rapidly after the first dose, but full benefit may require repeated doses.

North American Spine Society

In 2020, the North American Spine Society guideline on the diagnosis and treatment of low back pain states that evidence is insufficient to make a recommendation for or against treatment with trigger point injections (Grade I recommendation – insufficient or conflicting evidence not allowing a recommendation for or against the intervention).^{12,} Neural therapy and local anesthetic injections are not specifically mentioned, but the guideline reviewed 1 randomized study (Level II evidence) that compared a single treatment with lidocaine, lidocaine combined with a steroid, a dry needle (acupuncture), and vapocoolant spray plus acupressure.^{13,} After 2 weeks, pain was improved by 40% to 60% in all groups. Based on this study, the guideline authors concluded that outcomes are similar regardless of the medication used for the trigger point injection.

U.S. Preventive Services Task Force Recommendations

Not applicable.

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 ongoing and unpublished trials that may influence this review are listed in Table 1.

Table 1. Ongoing and Unpublished Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT03936309 A Comparison of Scar Infiltration, Scar Deactivation, and Standard of Care for the Treatment of Chronic,		60	May 2024

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NCT No.	Trial Name	Planned Enrollment	Completion Date
	Post-Surgical Pain After Cesarean Section in the Primary Care Setting: A Comparative Effectiveness Trial		
Unpublished			
NCT04509440	Efficacy of Neural Prolotherapy Versus Local Corticosteroid Soft Tissue Injection for Treatment of Anserine Bursitis	43	Oct 2019

References

- Frank BL. Neural therapy. Phys Med Rehabil Clin N Am. Aug 1999; 10(3): 573-82, viii. PMID 10516978
- Bölük Şenlikci H, Odabaşı ÖS, Ural Nazlıkul FG, et al. Effects of local anaesthetics (neural therapy) on pain and hand functions in patients with De Quervain tenosynovitis: A prospective randomised controlled study. Int J Clin Pract. Oct 2021; 75(10): e14581. PMID 34185386
- 3. Altınbilek T, Terzi R, Başaran A, et al. Evaluation of the effects of neural therapy in patients diagnosed with fibromyalgia. Turk J Phys Med Rehabil. Mar 2019; 65(1): 1-8. PMID 31453538
- Nazlıkul H, Ural FG, Öztürk GT, et al. Evaluation of neural therapy effect in patients with piriformis syndrome. J Back Musculoskelet Rehabil. 2018; 31(6): 1105-1110. PMID 30010101
- 5. Montenegro ML, Braz CA, Rosa-e-Silva JC, et al. Anaesthetic injection versus ischemic compression for the pain relief of abdominal wall trigger points in women with chronic pelvic pain. BMC Anesthesiol. Dec 01 2015; 15: 175. PMID 26628263
- 6. Balevi Batur E, Atan T. Neural therapy for fibromyalgia: Myth or improving quality of life?. Int J Clin Pract. Apr 2021; 75(4): e13719. PMID 32955788
- 7. Egli S, Pfister M, Ludin SM, et al. Long-term results of therapeutic local anesthesia (neural therapy) in 280 referred refractory chronic pain patients. BMC Complement Altern Med. Jun 27 2015; 15: 200. PMID 26115657
- 8. Atalay NS, Sahin F, Atalay A, et al. Comparison of efficacy of neural therapy and physical therapy in chronic low back pain. Afr J Tradit Complement Altern Med. 2013; 10(3): 431-5. PMID 24146471
- 9. Yadav V, Bever C, Bowen J, et al. Summary of evidence-based guideline: complementary and alternative medicine in multiple sclerosis: report of the guideline development subcommittee of the American Academy of Neurology. Neurology. Mar 25 2014; 82(12): 1083-92. PMID 24663230
- Gibson RG, Gibson SL. Neural therapy in the treatment of multiple sclerosis. J Altern Complement Med. Dec 1999; 5(6): 543-52. PMID 10630348
- 11. Chronic Pelvic Pain: ACOG Practice Bulletin, Number 218. Obstet Gynecol. Mar 2020; 135(3): e98-e109. PMID 32080051
- 12. North American Spine Society. Diagnosis and treatment of low back pain. 2020. Accessed September 14, 2023.
- 13. Garvey TA, Marks MR, Wiesel SW. A prospective, randomized, double-blind evaluation of trigger-point injection therapy for low-back pain. Spine (Phila Pa 1976). Sep 1989; 14(9): 962-4. PMID 2528826

Documentation for Clinical Review

No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy.

The following codes are included below for informational purposes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy. Policy Statements are intended to provide member coverage information and may include the use of some codes for clarity. The Policy Guidelines section may also provide additional information for how to interpret the Policy Statements and to provide coding guidance in some cases.

Type	Code	Description		
	20550	Injection(s); single tendon sheath, or ligament, aponeurosis (e.g., plantar		
	20550	"fascia")		
	20551	Injection(s); single tendon origin/insertion		
	20552	Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s)		
	20553	Injection(s); single or multiple trigger point(s), 3 or more muscles		
	64400	Injection, anesthetic agent; trigeminal nerve, any division or branch		
	64402	Injection, anesthetic agent; facial nerve		
	64405	Injection, anesthetic agent; greater occipital nerve		
	64408	Injection, anesthetic agent; vagus nerve		
	64410	Injection, anesthetic agent; phrenic nerve		
	64413	Injection, anesthetic agent; cervical plexus		
	64415	Injection, anesthetic agent; brachial plexus, single		
	64416	Injection, anesthetic agent; brachial plexus, continuous infusion by		
	04410	catheter (including catheter placement)		
	64417	Injection, anesthetic agent; axillary nerve		
	64418	Injection, anesthetic agent; suprascapular nerve		
	64420	Injection, anesthetic agent; intercostal nerve, single		
CD-0	64421	Injection, anesthetic agent; intercostal nerves, multiple, regional block		
CPT®	64425	Injection, anesthetic agent; ilioinguinal, iliohypogastric nerves		
	64430	Injection, anesthetic agent; pudendal nerve		
	64435	Injection, anesthetic agent; paracervical (uterine) nerve		
	64445	Injection, anesthetic agent; sciatic nerve, single		
	64446	Injection, anesthetic agent; sciatic nerve, continuous infusion by catheter		
		(including catheter placement)		
	64447	Injection, anesthetic agent; femoral nerve, single		
	64448	Injection, anesthetic agent; femoral nerve, continuous infusion by		
		catheter (including catheter placement)		
	64449	Injection, anesthetic agent; lumbar plexus, posterior approach,		
		continuous infusion by catheter (including catheter placement)		
	64450	Injection, anesthetic agent; other peripheral nerve or branch		
	64479	Injection(s), anesthetic agent and/or steroid, transforaminal epidural,		
	04479	with imaging guidance (fluoroscopy or CT); cervical or thoracic, single level		
		Injection(s), anesthetic agent and/or steroid, transforaminal epidural,		
		with imaging guidance (fluoroscopy or CT); cervical or thoracic, each		
	64480	additional level (List separately in addition to code for primary		
		procedure)		
		1.		

Туре	Code	Description
	64483	Injection(s), anesthetic agent and/or steroid, transforaminal epidural,
		with imaging guidance (fluoroscopy or CT); lumbar or sacral, single level
		Injection(s), anesthetic agent and/or steroid, transforaminal epidural,
	64484	with imaging guidance (fluoroscopy or CT); lumbar or sacral, each
	04404	additional level (List separately in addition to code for primary
		procedure)
	64505	Injection, anesthetic agent; sphenopalatine ganglion
	64508	Injection, anesthetic agent; carotid sinus (separate procedure)
	64510 Injection, anesthetic agent; stellate ganglion (cervical sympatheti function, anesthetic agent; superior hypogastric plexus	
	64520	Injection, anesthetic agent; lumbar or thoracic (paravertebral
	04320	sympathetic)
	64530	Injection, anesthetic agent; celiac plexus, with or without radiologic
	04330	monitoring
	96372	Therapeutic, prophylactic, or diagnostic injection (specify substance or
303/2		drug); subcutaneous or intramuscular
	99199	Unlisted special service, procedure or report
HCPCS	None	

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	
03/01/2016	BCBSA Medical Policy adoption	
05/01/2017	Policy revision without position change	
01/01/2018	Policy revision without position change	
01/01/2019	Policy revision without position change. Coding update	
02/01/2024	Policy reactivated. Previously archived from 04/01/2020 to 01/31/2024.	

Definitions of Decision Determinations

Medically Necessary: Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will

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be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements and Feedback (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

We are interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration.

For utilization and medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. 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 covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT		
BEFORE AFTER		
	Blue font: Verbiage Changes/Additions	
Reactivated Policy	Neural Therapy 2.01.85	
Policy Statement: N/A	Policy Statement: I. Neural therapy is considered investigational for all indications.	