Neural Therapy is considered investigational for all indications.

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.

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, transformaminal epidural, with imaging guidance by spinal region
- **64505-64530**: Code range for injection, anesthetic agent into autonomic nerves/ganglia
- **96372**: Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular

The following CPT code might always be used:

- **99199**: Unlisted special service, procedure or report

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, 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
- Intravenous Anesthetics for the Treatment of Chronic Pain
- 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.
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, two domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one 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.

**Neural Therapy**

Neural therapy is an alternative medicine modality that was developed in Germany and is most commonly reported in Europe. Most of the literature on neural therapy consists of non-English-language publications.
Clinical Context and Therapy Purpose
The purpose of neural therapy in patients who have chronic pain or illness is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does the use of neural therapy improve the net health outcome in patients with chronic pain or illness?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant population of interest is individuals with chronic pain or illness.

Interventions
The therapy being considered is neural therapy.

Comparators
The following practice is currently being used to treat chronic pain or illness: standard medical management.

Outcomes
The general outcomes of interest are improvements in functional outcomes and reductions in pain or illness as well as medication use.

Timing
Follow-up varies by indication and by the number of injections required. Treatment may require a single or series of anesthetic injections over weeks or months.

Setting
Neural therapy injections are administered in an outpatient setting.

Randomized Controlled Trials
Hui et al (2012) reported a nonblinded randomized controlled trial of complementary and alternative medicine for chronic herpes zoster-related pain. The 59 patients included in the trial had a confirmed diagnosis of herpes zoster of at least 30 days in duration (median, 4.8 months; range, 1 month to 15 years) and with at least moderate postherpetic neuralgia pain (≥4 on a 10-point Likert scale). The therapy included 3 weeks of neural therapy (injection of 1% procaine at up to 6 points along the affected dermatome) along with other therapies from traditional Chinese medicine (i.e., acupuncture, cupping and bleeding, Chinese herbs) and meditation. A wait-list control group received the same treatment beginning 3 weeks after randomization. Intention-to-treat analysis of pain scores at 3 weeks showed significant improvement in the complementary and alternative medicine group (baseline, 7.5; posttreatment, 2.3), with little change in the wait-list control group (baseline, 7.8; 3 weeks, 7.2). A reduction in pain of at least 50% was observed in 66.7% of patients in the treatment group compared with 8.7% in the control group. In the 56% of patients who responded to a questionnaire after 1 to 2 years, 78.8% reported continued relief of pain. Interpretation of the results is limited by the multiple interventions provided and the possibility of a placebo effect in this nonblinded study.

One English-language report by Gibson and Gibson (1999) described a small double-blind, randomized, placebo-controlled crossover trial in 21 patients with multiple sclerosis. Anesthetic or saline was injected at acupuncture points in the ankle and at 14 or 15 points around the circumference of the head. Patients received 2 injections of anesthetic or saline in the first week; in the second week, all patients received anesthetic injections. At the end of the first week, 8 of 11 patients in the active treatment group and 1 of 10 in the placebo group had improved in 1 or more functions on the Kurtzke scale. Therapy was continued as needed for up to 3.5 years, with long-term improvements being reported in over 50% of patients.
Nonrandomized Trials
Egli et al (2015) reported on a series of 280 patients with chronic severe pain who had failed conventional medical measures. The most common reason for referral to the academic center in Europe was back pain, and more than two-thirds of patients had undergone physical therapy (PT), osteopathy, or chiropractic. After an average of 9.2 treatments (range, 1-40) 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. 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, lack of comparability between groups at baseline, and lack of a placebo control.

Schmittinger et al (2011) reported on a case of brainstem hemorrhage following neural therapy for decreased libido.

Summary of Evidence
For individuals who have chronic pain or illness (e.g., pain, 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, skin and circulation problems) who receive neural therapy, the evidence includes small randomized trials and a large case series. Relevant outcomes are symptoms, functional outcomes, quality of life, medication use, and treatment-related morbidity. There are few English-language reports assessing the use of neural therapy for pain, and the available studies have methodologic limitations that preclude conclusions on efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information
Practice Guidelines and Position Statements
The American Association of Orthopaedic Medicine has described neural therapy on its website and provides a link for instructional courses on the procedure.

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
A search of ClinicalTrials.gov in October 2018 did not identify any ongoing or unpublished trials that would likely influence this review.
References


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. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

IE

The following services may be considered investigational.

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<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT®</td>
<td>20550</td>
<td>Injection(s); single tendon sheath, or ligament, aponeurosis (e.g., plantar &quot;fascia&quot;)</td>
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<td>Injection(s); single tendon origin/insertion</td>
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<td>Injection(s); single or multiple trigger point(s), 1 or 2 muscle(s)</td>
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<td>20553</td>
<td>Injection(s); single or multiple trigger point(s), 3 or more muscles</td>
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<td>Injection, anesthetic agent; greater occipital nerve</td>
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<td>Injection, anesthetic agent; lumbar or thoracic (paravertebral sympathetic)</td>
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<td>96372</td>
<td>Therapeutic, prophylactic, or diagnostic injection (specify substance or drug); subcutaneous or intramuscular</td>
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<tr>
<td></td>
<td>99199</td>
<td>Unlisted special service, procedure or report</td>
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</tbody>
</table>

**HCPCS**

None

**ICD-10 Procedure**

None

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**Policy History**

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

**Medically Necessary:** A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

**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 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 (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. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

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.