MEDICAL POLICY

Capital BLUE

POLICY TITLE	SYMPATHETIC THERAPY FOR THE TREATMENT OF PAIN
POLICY NUMBER	MP-6.045

Original Issue Date (Created):	**October 25, 2011**
Most Recent Review Date (Revised):	**January 28, 2014**
Effective Date:	**April 1, 2014**

I. POLICY

Sympathetic therapy is considered **investigational** for treatment of pain as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-references:
MP-6.020 Transcutaneous Electrical Nerve Stimulation
MP-6.046 Threshold Electrical Stimulation as a Treatment of Motor Disorders
MP-6.047 Interferential Stimulation for Treatment of Pain
MP-6.048 Electrical Stimulation for the Treatment of Arthritis and Miscellaneous Conditions
MP-6.049 H-Wave Electrical Stimulation
MP-6.050 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy
MP-6.051 Neuromuscular and Functional Neuromuscular Electrical Stimulation

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids
[N] PPO
[N] HMO
[N] SeniorBlue HMO
[N] SeniorBlue PPO
[N] Indemnity
[N] SpecialCare
[N] POS
[Y] FEP PPO*

*The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

[Note: Final page is signature page and is kept on file, but not issued with Policy.]

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III. DESCRIPTION/BACKGROUND

Sympathetic therapy describes a type of electrical stimulation of the peripheral nerves that is designed to stimulate the sympathetic nervous system in an effort to "normalize" the autonomic nervous system and alleviate chronic pain. Unlike TENS (transcutaneous electrical nerve stimulation) or interferential electrical stimulation, sympathetic therapy is not designed to treat local pain, but is designed to induce a systemic effect on sympathetically induced pain.

Sympathetic therapy uses 4 intersecting channels of various frequencies with bilateral electrode placement on the feet, legs, arms, and hands. Based on the location of the patient's pain and treatment protocols supplied by the manufacturer, electrodes are placed in various locations on the lower legs and feet or the hands and arms. Electrical current is then induced with beat frequencies between 0 and 1000 Hz. Treatment may include daily 1-hour treatments in the physician's office, followed by home treatments, if the initial treatment is effective.

The Dynatron STS device and a companion home device, Dynatron STS Rx (Dynatronics Corporation), are devices that deliver sympathetic therapy. These devices received U.S. Food and Drug Administration (FDA) clearance in March 2001 through a 510(k) process. The FDA-labeled indication is as follows:

"Electrical stimulation delivered by the Dynatron STS and Dynatron STS Rx is indicated for providing symptomatic relief of chronic intractable pain and/or management of post-traumatic or post-surgical pain."

IV. RATIONALE

Ideally, assessment of therapies designed to treat chronic pain should be based on placebo-controlled trials to assess the magnitude of the expected placebo effect and to isolate the contribution of the active treatment. Outcomes of interest might include changes in scores of a visual analog scale (VAS), quality of life measures such as an SF-36, reduction in pain medications, daily activity levels, or return to work. However, a MEDLINE search did not identify any studies published in the peer-reviewed literature regarding sympathetic therapy.

An information packet from the manufacturer Dynatronics (Salt Lake City, UT) (1) includes 2 articles also referenced in their promotional material. Although these 2 articles have not been published in the peer-reviewed literature, they are briefly reviewed below.

1. Sacks and colleagues reported on a retrospective study of 197 patients with chronic pain of various origins including upper and lower extremity pain and migraine. Some patients reported multiple sites of pain, and each different site of pain was registered as a separate pain complaint, resulting in 227 patient records. Of these, 91% reported mild pain relief, with 33% reporting complete pain relief.

A total of 78% reported an increase in their daily living activities by 50% or more, and 69% reported a decrease in medications. No data were reported regarding the various etiologies of pain, prior treatment including baseline drug requirements, exact treatment protocol, the number of treatments, or how pain relief, activities of daily living, or other treatment outcomes were evaluated. There was no control group.

2. Guido reported on the effects of sympathetic therapy in 20 volunteers suffering from chronic pain related to peripheral neuropathy. The treatment protocol varied with the site of pain, i.e., upper versus lower extremity, and could vary from day to day. Patients underwent daily therapy for 28 days. At the end of the study, the mean global VAS scores were significantly reduced, although these data are not presented in a table or figure. There was no control group.

2004-2005 Update

A review of the peer-reviewed literature on MEDLINE from the period of 2002 through June 2005 found no published articles on sympathetic therapy for chronic pain other than the Guido study listed here, which was subsequently published. (2) Therefore, the policy is unchanged.

2006 Update

A search of the MEDLINE database for the period of April 2005 through September 2006 retrieved no published studies on sympathetic therapy. Updated guidelines from the Work Loss Data Institute list sympathetic therapy as an intervention that is currently under study and not specifically recommended. (3) Therefore, the policy is unchanged.

2007-2013 Update

A search of the MEDLINE database for the period of October 2006 through October 2013 did not identify any studies on sympathetic therapy. Therefore, the policy statement is unchanged.

V. DEFINITIONS

510 (K) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

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VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. REFERENCES

American College of Occupational and Environmental Medicine. Chronic pain. In: Occupational medicine practice guidelines: evaluation and management of common health problems and functional recovery in workers. Elk Grove Village (IL): American College of Occupational and Environmental Medicine (ACOEM); 2008. p. 73-502.

Dynatronics. [Website]: http://www.chronicpainrx.com/. Accessed October 28, 2013.

Work Loss Data Institute. Pain (chronic), Updated June 10, 2011; National Guideline Clearinghouse [Website]: http://www.guideline.gov/content.aspx?id=33188 Accessed October 28, 2013.

IX. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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Sympathetic therapy for the treatment of pain is investigational; therefore the following codes are not covered when used for sympathetic therapy for the treatment of pain:

CPT Codes®								
97014	97032							

HCPCS Code	Description
A9900	Miscellaneous DME supply, accessory, and/or service component of another HCPCS code may be used
E0730	Transcutaneous electrical nerve stimulation (TENS) device, 4 or more leads, for multiple nerve stimulation

X. POLICY HISTORY

MP-6.045	**CAC 10/25/11** Removed information regarding sympathetic therapy for treatment of pain from MP-6.020, Electrical Stimulation Modalities and created a separate policy. Adopted BCBSA. No change in policy statement, remains investigational.
	CAC 1/29/13 Consensus review. References updated; no changes to the policy statement. Codes reviewed 11/29/12 klr
	CAC 1/28/14 Consensus review. References updated; no changes to the policy statements. Rationale added**.**