Sympathetic Therapy for the Treatment of Pain

Archived Medical Policy

Archived medical policies are no longer subject to periodic review, are maintained for reference, and may be returned to active status if the need is identified.

Policy # 00114
Original Effective Date: 08/20/2001
Archived Date: 06/20/2012

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the “Company”), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Services Are Considered Investigational
Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers sympathetic therapy to be investigational.*

Background/Overview
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 four 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 1,000 Hz. Treatment may include daily one-hour treatments in the physician's office, followed by home treatments if the initial treatment is effective.

FDA or Other Governmental Regulatory Approval
U.S. Food and Drug Administration (FDA)
The Dynatron® STS™ device and a companion home device, Dynatron® STS Rx™, are devices that deliver sympathetic therapy. These devices received 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.”

Rationale/Source
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
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Treatment. Outcomes of interest might include changes in scores of a visual analog scale, 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 Dynatron (Salt Lake City, UT) includes two articles also referenced in their promotional material. Although these two 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.

2006 Update
A search of the MEDLINE database for the period of 2002 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. Therefore, the policy is unchanged.

2007-2008 Update
A search of the MEDLINE database for the period of October 2006 through January 2008 did not identify any studies on sympathetic therapy. Therefore, the policy statement is unchanged.

References
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Coding

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

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Policy History

Original Effective Date: 08/20/2001
08/16/2001 Medical Policy Committee review
08/20/2001 Managed Care Advisory Council approval
07/15/2003 Medical Policy Committee review
08/03/2005 Medical Director review
08/24/2005 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.
06/04/2009 Medical Director review
06/17/2009 Medical Policy Committee approval. Coverage eligibility unchanged.
06/03/2010 Medical Policy Committee review
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06/16/2010  Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
06/02/2011  Medical Policy Committee review
06/14/2012  Medical Policy Committee review
Next Scheduled Review Date: Archived.

*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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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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