



BlueCross BlueShield
of Alabama

Name of Policy:

**Sympathetic Therapy and Bioelectrical Nerve Block or
Electroanalgesic Nerve Block for the Treatment of Pain**

Policy #: 015
Category: Therapy

Latest Review Date: February 2010
Policy Grade: **Active Policy but no
longer scheduled for
regular literature
reviews and updates.**

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

- 1. The technology must have final approval from the appropriate government regulatory bodies;*
- 2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
- 3. The technology must improve the net health outcome;*
- 4. The technology must be as beneficial as any established alternatives;*
- 5. The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

- 1. In accordance with generally accepted standards of medical practice; and*
- 2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
- 3. Not primarily for the convenience of the patient, physician or other health care provider; and*
- 4. 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 that patient's illness, injury or disease.*

Description of Procedure or Service:

Sympathetic therapy is a method of administering electrical current through the peripheral nerves of the lower legs and feet as well as the arms and hands creating a unique form of stimulation of the sympathetic nervous system. The effect of Sympathetic Therapy is to normalize the sympathetic nervous system resulting in relief of chronic intractable pain. The Sympathetic Therapy protocol uses four intrasecting stimulation channels of various frequencies (8 electrodes per treatment) with specific electrode placement on the feet, legs, arms, and hands. Treatment lasts for approximately one hour. Multiple beat frequencies are generated between 0-1,000 Hz. Electrodes are applied bilaterally following the peripheral nerve pathways from one side of the body to the other crossing the spine. Therapy is delivered using the Dynatron STS device during the treatment plan development. There are over 300 treatment protocols to choose from, therefore, the clinician will select the most appropriate protocol based on multiple factors including the location, and severity of the pain. Adjustments to the treatment protocol continue to be made during the treatment plan development. Usually, ten or more clinical treatments are required to complete the treatment plan. Once the treatment plan has become developed, the Dynatron STS Rx home therapy device can be utilized to maintain pain relief. The Dynatron STS (Dynatronics Corporation, manufacturer) device and a companion home device, Dynatron STS Rx, 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 the Dynatron STS Rx is indicated for providing symptomatic relief of chronic intractable pain and/or management of post-traumatic or post-surgical pain."

Electroceutical therapy, also known as bioelectric nerve block or electroanalgesic nerve block, involves blockade of axonal transmissions. Electroceutical therapy has been used in the management of both non-malignant and malignant pain, acute and chronic pain. Electroceutical medicine entails the use of various electrical modalities. Electroceutical treatments use much higher electrical frequencies than transcutaneous electrical nerve stimulation (TENS) and are only prescribed and administered per a healthcare provider with expertise in this type of therapy. This Electroceutical therapy is also known as bioelectric therapy, non-invasive neuron-blockade device, electroceutical neuron-blockade devices and bioelectric treatment. One manufacturer of this electroceutical equipment is Biotronics Research and the device is known as Matrix II.

Policy:

Sympathetic Therapy does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**.

Electroceutical therapy or electroanalgesic nerve block does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and is considered **investigational**. There is a lack of scientific evidence regarding the effectiveness of this technology.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the

members' contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

Literature that was submitted for review contained two abstracts without documentation of being published. Millions of people suffer from the effects of chronic pain. It has been documented that 1 in every 5 Americans report suffering from chronic pain and that 7 of 10 of these people say it interferes with their daily lives. Dynatron therapy is reported to provide a non-invasive alternative with promising results. In one abstract, 197 patients who presented with chronic pain of various origins were treated using this therapy. Thirty-three of the patients reported receiving total pain relief. An additional 58% of the patients reported mild to significant reductions in pain. The average pain reduction for these individuals was 63%. Duration of the relief was varied. Eighty-three percent of the patients achieving relief and available for follow-up continued to maintain the same or greater levels of pain relief 90 days following treatment. (Sacks, et al.)

In the second study, 20 volunteers suffering from chronic pain received the Sympathetic Therapy. Most of these individuals had specified their pain being caused from peripheral neuropathies. The subjects ranged in age from 37-75 and were treated on a daily basis for 28 days. Seventy-three percent of the responding subjects reported moderate to severe pain. By the end of the study, only 1/3 of the subjects reported moderate to severe pain. Fifty percent of the patients reported total pain relief. Eighty percent of the patients reported an improvement in their quality of life as well as 40% being able to reduce their pain medication. The quantification of the pain reduction was derived from the analysis of the visual analog scales. (Guido, Ernesto)

There are no published randomized controlled clinical trials of the effectiveness of Sympathetic Therapy in the management of patients with chronic intractable pain.

Electroceutical therapy is a non-invasive application of controlled, specific parameter bioelectric impulses. Electrical current is altered through special step-down transformers into bioelectric impulses. According to the manufacturer of one of the devices, these unique impulses enhance and encourage cellular activity deep within the tissues. Electrodes are placed in pairs directly on the skin. The proper electroceutical class, dosage, regimen duration and anatomical placement of electrodes are determined by the individual patient's diagnosis.

There remains a lack of scientific evidence to substantiate the validity of the claims of relief of pain and elimination or drastic reductions in pain medication requirements. Well-designed, randomized controlled clinical studies are needed to determine the usefulness of electroceutical therapy in the treatment of patients with acute or chronic pain.

February 2007 Update

No new literature was located that would alter the policy statement. The policy statement remains unchanged.

February 2008 Update

No new published peer-reviewed literature was located that would alter the coverage statement on this policy.

February 2009 Update

A literature search identified no new studies on sympathetic therapy or electroceutical therapy.

February 2010 Update

A literature search identified no new studies that would alter the coverage statement of this policy. This policy will be archived. Coverage will remain investigational, no further updates.

Key Words:

Sympathetic Therapy, Dynatron STS™, Dynatron STS Rx™, electroceutical therapy, bioelectric nerve block, non-invasive neuron-blockade devices, electroceutical neuron-blockade devices, electric analgesic nerve block

Approved by Governing Bodies:

Dynatron STS received U.S. Food and Drug Administration (FDA) clearance in March 2001 through a 510(k) process.

Matrix II is approved for sale in Canada

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

ITS Home: No special consideration

ITS Host: Not subject to Alabama bundling edits

FEP contracts: FEP does not consider investigational if FDA approved. Will be reviewed for medical necessity.

Pre-certification/Pre-determination requirements: Not applicable

Coding:

CPT: At this time there are not specific CPT/HCPCS codes for this service.

Physical Therapy for the treatment plan:

97799 Unlisted physical medicine rehab service or procedure

Manufacturer suggested: **64999** Unlisted procedure, nervous system.

HCPCS: **E1399** Unlisted Durable Medical Equipment

References:

1. Blue Cross and Blue Shield Association. Medical Policy Reference Manual. *Sympathetic Therapy for the Treatment of Pain*, February 2005.
2. Dynatronix, May 29, 2001, www.chronicpainrx.com/dynatron.
3. Guido, M.D., Ernesto H. *Effects of sympathetic therapy on chronic pain in peripheral neuropathy subjects*.
4. Sacks, M.D., Steven M., et al. *Retrospective study of sympathetic therapy for pain attenuation in 197 patients*.
5. Schwartz Robert G. *Electric sympathetic block: Current theoretical concepts and clinical results*, Journal of Back and Musculoskeletal Rehabilitation 1998; 10: 31-46.

Policy History:

Medical Policy Group, July 2001

Medical Policy Group, January 2003

Medical Policy Group, February 2004

Medical Policy Group, September 2005 **(1)**

Medical Policy Administration Committee, October 2005

Available for comment October 12-November 28, 2005

Medical Policy Group, February 2006 **(1)**

Medical Policy Administration Committee, March 2006

Medical Policy Group, February 2007 **(1)**

Medical Policy Group, February 2008 **(1)**

Medical Policy Group, February 2009 **(1)**

Medical Policy Group, February 2010 (1) Active Policy but no longer scheduled for regular literature reviews and updates effective February 23, 2010.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case by case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.