Name of Blue Advantage Policy:
Sympathetic Therapy and Bioelectrical Nerve Block or Electroanalgesic Nerve Block for the Treatment of Pain

Policy #: 015
Category: DME, Therapy

Latest Review Date: June 2019
Policy Grade: Effective March 2, 2010: Active Policy but no longer scheduled for regular literature reviews and updates.

Background:
Blue Advantage medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:

1. Safe and effective;
2. Not experimental or investigational*;
3. Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:
   • Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member;
   • Furnished in a setting appropriate to the patient’s medical needs and condition;
   • Ordered and furnished by qualified personnel;
   • One that meets, but does not exceed, the patient’s medical need; and
   • At least as beneficial as an existing and available medically appropriate alternative.

*Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill Original Medicare for covered services that are related to clinical trials that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).
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 intersecting 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:
Effective for dates of service on or after July 1, 2005:
Blue Advantage will treat Sympathetic Therapy as a non-covered benefit and as investigational.

Blue Advantage will treat electroceutical therapy or electroanalgesic nerve block as a non-covered benefit and as investigational. There is a lack of scientific evidence regarding the effectiveness of this technology.

Blue Advantage 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 Advantage Medical Policy #015
Advantage administers benefits based on the members' contract and 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)

Updated guidelines from the Work Loss Data Institute list sympathetic therapy as an intervention that is currently under study and not specifically recommended.

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.

June 2019 Update
A search of peer reviewed literature identified no new clinical trial publications or any additional information that would change the coverage position of this medical policy.

Key Words:
Sympathetic Therapy, Dynatron STSTM, Dynatron STS RxTM, electroceutical therapy, bioelectric nerve block, non-invasive neuron-blockade devices, electroceutical neuron-blockade devices, electric analgesic nerve block, bioelectric treatment systems

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.

CURRENT 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:

Policy History:
Adopted for Blue Advantage, March 2005
Available for comment May 1-June 14, 2005
Medical Policy Group, September 2005
Available for comment October 13-November 28, 2005
Medical Policy Group, February 2007
Medical Policy Group, February 2008
Medical Policy Group, February 2009
Medical Policy Group, March 2010: Active Policy but no longer scheduled for regular literature reviews and updates.
Medical Policy Group, June 2019

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.