Effective November 1, 2023, refer to CMS Manual 100-02, Chapter 16-General Exclusions from Coverage for services included in this policy.

BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

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

Policy #: 015
Latest Review Date: July 2023
Category: Therapy
ARCHIVED EFFECTIVE 11/1/2023

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).*

POLICY:

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**.

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 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.

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.

KEY POINTS:

The most recent literature search was performed through July 11, 2023.

Summary of Evidence

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.

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.

U.S. Preventative Services Task Force Recommendations

Not applicable.

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, 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 Codes:

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 CPT Code:

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. Dynatronics, 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.
6. Work Loss Data Institute. Pain 2006; National Guideline Clearinghouse. Available at: www.guideline.gov.

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
Medical Policy Group, July 2021

Medical Policy Group, June 2022: Reviewed by consensus. A peer-reviewed literature analysis was completed and no new information was identified that would alter the coverage statement of this policy.
Medical Policy Group, July 2023: Reviewed by consensus. A peer-reviewed literature analysis was completed, and no new information was identified that would alter the coverage statement of this policy.
Medical Policy Group, November 2023: Archived effective 11/1/2023.
