



**BlueCross BlueShield
of Alabama**

Name of Policy:

Threshold Electrical Stimulation as a Treatment of Motor Disorders

Policy #: 157

Category: Durable Medical Equipment (DME)

Latest Review Date: January 2014

Policy Grade: Active Policy but no
longer scheduled for
regular literature
reviews and updates.

Background:

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:

Threshold electrical stimulation is provided by a small electrical generator, lead wires, and surface electrodes that are placed over the targeted muscles. The intensity of the stimulation is set at the sensory threshold and does not cause a muscle contraction.

Threshold electrical stimulation is described as the delivery of low intensity electrical stimulation to target spastic muscles during sleep at home. The stimulation is not intended to cause muscle contraction. Although the mechanism of action is not understood, it is thought that low intensity stimulation may increase muscle strength and joint mobility, leading to improved voluntary motor function. The technique has been used most extensively in children with spastic diplegia related to cerebral palsy (CP), where the patient may have disuse atrophy. It has also been used with other motor disorders, such as spina bifida, brachial plexus injuries, central nervous system injuries, post-polio syndrome, and idiopathic scoliosis.

The TES device is a small battery powered unit with two lead wires, and each of these has two electrodes attached at the ends. These electrodes are attached to certain areas of the skin. The technique involves the administration of small electrical stimuli to the skin overlying selected "weakened" muscles that are usually opposite the spastic muscles. TES is thought to work by increasing local blood flow, and along with the nightly secretion of trophic hormones, to enlarge the atrophic muscles and improve motor function. TES is usually applied six nights per week (8-12 hours per night) for two to four years. TES is not a substitute for other therapies, but should be used as an adjunct to an established physical therapy program. Mayatek of Toronto, Canada, manufactures one type of TES unit.

Policy:

Threshold Electrical Stimulation (TES), as a treatment of motor disorders including but not limited to cerebral palsy, spina bifida, idiopathic scoliosis, or brachial plexus injuries, **does not meet** Blue Cross and Blue Shield of Alabama's medical criteria for coverage.

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:

The most recent literature search was performed through August 2013. The following is a summary of the key literature to date.

Validation of therapeutic electrical stimulation requires randomized, controlled studies that can isolate the contribution of the electrical stimulation from other components of therapy. Physical therapy is an important component of the treatment of cerebral palsy and other motor disorders.

Therefore, trials of threshold electrical stimulation ideally should include standardized regimens of physical therapy. Randomized studies using sham devices are preferred to control for any possible placebo effect.

A randomized study published in 1997 included 44 patients with spastic cerebral palsy who had undergone a selective posterior lumbosacral rhizotomy at least one year previously. All patients had impaired motor function, but some form of upright ambulation. Patients were randomly assigned to receive either a 12-month period of 8 to 12 hours of nightly electrical stimulation or no therapy. The principal outcome measure was the change from baseline to 12 months in the Gross Motor Function Measure (GMFM), as assessed by therapists blinded to the treatment. The patients and their parents were not blinded; the authors stated that the active device produced a tingling sensation that precluded a double-blind design. Patients were encouraged to maintain whatever ongoing therapy they were participating in. The type of physical therapy in either the control or treatment group was not described.

After one year, the mean change in the GMFM was 5.5% in the treated group, compared to 1.9% in the control group, a statistically significant difference. The authors state that this 3.6% absolute difference is clinically significant. For example, a child who was previously only able to rise and stand while pushing on the floor could now do so without using hands. While these results point to a modest benefit, the lack of control for associated physical therapy limits the interpretation.

Five additional studies were identified in the literature over the next ten years, none of them demonstrating effectiveness. Dali et al published the results of a trial that randomly assigned 57 children with cerebral palsy to receive either threshold electrical stimulation or a dummy device for a 12-month period. Visual and subjective assessments showed a trend in favor of the treatment group, while there was no significant effect of therapeutic electrical stimulation in terms of motor function, range of motion, or muscle size. The authors concluded that therapeutic electrical stimulation was not shown to be effective in this study.

Two smaller randomized controlled studies found no improvement in muscle strength with electrical stimulation. In the van der Linden et al. study, 22 children with cerebral palsy were randomly assigned to receive one hour of electrical stimulation to the gluteus maximus daily over a period of 8 weeks to improve gait. No clinical or statistically significant between group differences were found in measurements of hip extensor strength, gait analysis, passive limits of hip rotation, and section E of the GMFM. Fehlings et al also found no evidence of improved strength in 13 children with types II/III spinal muscular atrophy who were randomly assigned to either receive electrical stimulation or a placebo stimulator during a 12-month period. A study of 24 patients with cerebral palsy demonstrated positive results for the subset that received stimulation combined with dynamic bracing; however, the effect did not last after discontinuing treatment.

Kerr et al randomly assigned 60 children with cerebral palsy to one hour daily of neuromuscular stimulation (n=18), overnight threshold electrical stimulation (n=20), or overnight sham stimulation (n=22). Blinded assessment following 16 weeks of treatment showed no difference among the groups as measured by peak torque or by a therapist-scored gross motor function. A parental questionnaire on the impact of disability on the child and family showed improvement for the two active groups but not the sham control. Compliance in the threshold electrical stimulation group was 38%; compliance in the placebo group was not

reported. Retrospective analysis indicated that the study would require 110 to 190 subjects to achieve 80% power for measures of strength and function.

A 2006 systematic review of electrical stimulation or other therapies given after botulinum toxin injection, conducted by the American Academy for Cerebral Palsy and Developmental Medicine, concluded that the available evidence is poor.

April 2010 Update

A literature search from the Medline database failed to identify any new studies or other relevant publications. The policy statement remains unchanged.

June 2011 Update

The studies published to date demonstrate that the threshold electrical stimulation is not effective treatment of spasticity, muscle weakness, reduced joint mobility or motor function, therefore, the policy statement has been changed from investigational to: does not meet medical criteria for coverage.

November 2011 Update

The National Institute of Neurological Disorders and Stroke states that threshold electrical stimulation is a controversial therapy and that studies have not been able to demonstrate its effectiveness or any significant improvement with its use.

November 2012 Update

No new studies identified for review.

Practice Guidelines and Positions Statements

According to the National Institute of Neurological Disorders and Stroke, many children and adolescents with cerebral palsy use some form of complementary or alternative medicine. Controlled clinical trials involving some of the therapies have been inconclusive or showed no benefit, and the therapies have not been accepted in mainstream clinical practice. Although there are anecdotal reports of some benefit in some children with cerebral palsy, these therapies have not been approved by the U.S. food and Drug Administration for the treatment of cerebral palsy. Such therapies include hyperbaric oxygen therapy, special clothing worn during resistance exercise training, certain forms of electrical stimulation, assisting children in completing certain motions several times a day, and specialized learning strategies.

Key Words:

Threshold Electrical Stimulation (TES), cerebral palsy, spina bifida, idiopathic scoliosis, brachial plexus injuries

Approved by Governing Bodies:

Devices used for threshold electrical stimulation are classified as “powered muscle stimulators”. As a class, the FDA describes these devices as “an electronically powered device intended for

medical purposes that repeatedly contracts muscles by passing electrical currents through electrodes contacting the affected body area”.

Benefit Application:

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

ITS: Home Policy provisions apply

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

Pre-certification/Pre-determination requirements: Not applicable

Current Coding:

CPT: **E0745*** Neuromuscular stimulator, electronic shock unit

* This code may also be used for other neuromuscular stimulators

References:

1. Dali C, et al. Threshold electrical stimulation (TES) in ambulant children with CP: A randomized double-blind placebo-controlled clinical trial, *Developmental Medicine and Child Neurology*, June 2002; 44: 364-369.
2. Durham T, et al. Surface electrical stimulation versus brace in treatment of idiopathic scoliosis, *Spine*, September 1990; 15(9): 888-892.
3. Fehlings DL, Kirsch S, et al. Evaluation of therapeutic electrical stimulation to improve muscle strength and function in children with types II/III spinal muscular atrophy. *Dev Med Child Neurol*, November 2002; 44(11): 741-744.
4. Kerr C, McDowell B, Cosgrove A, et al. Electrical stimulation in cerebral palsy: A randomized controlled trial. *Dev Med Child Neurol*, November 2006; 48(11): 868.
5. Lannin N, Scheinberg A and Clark K. AACPDM systematic review of the effectiveness of therapy for children with cerebral palsy after botulinum toxin A injections. *Dev Med Child Neurol* 2006; 48(6): 533-539.
6. Liron-Keshet S, Tirosh E, et al. The effect of therapeutic electrical stimulation in children with diplegic cerebral palsy as measured by gait analysis. *Basic Appl Myol* 2001; 11(3): 127-132.
7. Nachemson A and Peterson L. Effectiveness of treatment with a brace in girls who have adolescent idiopathic scoliosis. A prospective, controlled study based on data from the brace study of the scoliosis research society, *The Journal of Bone & Joint Surgery*, June 1995, Vol. 77-A(6), pp. 815-822.
8. O'Donnell C, et al. Electrical stimulation in the treatment of idiopathic scoliosis, *Clinical Orthopedics and Related Research*, April 1988, No. 229, pp. 107-113.
9. Ozer K, Chesher SP and Scheker LR. Neuromuscular electrical stimulation and dynamic bracing for the management of upper-extremity spasticity in children with cerebral palsy. *Dev Med Child Neurol* 2006; 48(7): 559-563.

10. Pape K, et al. Neuromuscular approach to the motor deficits of cerebral palsy: A pilot study, *Journal of Pediatric Orthopedics*, September 1993; 13(5): 628-33.
11. Semel-Concepcion J, et al. Neonatal brachial plexus palsies, <http://www.emedicine.com/pmr/topic215.htm>, Last accessed January 2014.
12. Sommerfelt K, et al. Therapeutic electrical stimulation in cerebral palsy: A randomized, controlled crossover trial, *Developmental Medicine and Child Neurology*, September 2001; 43(9): 609-613.
13. Steinbok P, et al. Therapeutic electrical stimulation following selective posterior rhizotomy in children with spastic diplegic cerebral palsy: A randomized clinical trial, *Developmental Medicine and Child Neurology*, 1997, Vol. 39, pp. 515-520.
14. The National Institute of Neurological Disorders and Stroke. *Cerebral Palsy: Hope through research*. Last updated June 13, 2011. Available online at: http://www.ninds.nih.gov/disorders/cerebral_palsy/detail_cerebral_palsy.htm#179393104. Last accessed January 2014.
15. van der Linden ML, Hazlewood ME, et al. Electrical stimulation of gluteus maximus in children with cerebral palsy: Effects on gait characteristics and muscle strength. *Dev Med Child Neurol*, June 2003; 45(6): 385-390.

Policy History:

Medical Policy Group, May 2004 (1)

Medical Policy Administration Committee, May 2004

Available for comment May 17-June 30, 2004

Medical Policy Group, April 2006 (1)

Medical Policy Group, April 2008 (1)

Medical Policy Group, April 2010 (1): No policy changes, references added

Medical Policy Panel, February 2011

Medical Policy Group, June 2011 (2): Description updated, Policy statement changed, revision of Key Points

Medical Policy Group, November 2011 (1): Update to Key Points and References; no change to policy statement

Medical Policy Group, November 2012 (1): Update to Key Points; no change to Policy statement.

Medical Policy Panel, October 2013

Medical Policy Group, January 2014 (2): No change to policy statement. Policy no longer scheduled for regular literature reviews.

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.