MEDICAL POLICY

POLICY TITLE	THRESHOLD STIMULATION AS A TREATMENT OF MOTOR DISORDERS
POLICY NUMBER	MP-6.046

Original Issue Date (Created):	**October 25, 2011**
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Effective Date:	**April 1, 2014**

I. POLICY

Threshold electrical stimulation as a treatment of motor disorders, including but not limited to cerebral palsy, is considered **not medically necessary**.

Cross-references:
MP-6.020 Transcutaneous Electrical Nerve Stimulation
MP- 6.045 Sympathetic Therapy for the Treatment of Pain
MP-6.047 Interferential Stimulation for Treatment of Pain
MP-6.048 Electrical Stimulation for the Treatment of Arthritis and Miscellaneous Conditions
MP-6.049 H-Wave Electrical Stimulation
MP-6.050 Percutaneous Electrical Nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy
MP-6.051 Neuromuscular and Functional Neuromuscular Electrical Stimulation

II. PRODUCT VARIATIONS

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

[N] Capital Cares 4 Kids
[N] PPO
[N] HMO
[N] SeniorBlue HMO
[N] SeniorBlue PPO
[N] Indemnity
[N] SpecialCare
[N] POS
[Y] FEP PPO*

*Refer to FEP Medical Policy Manual MP-1.01.19 Threshold Electrical Stimulation as a Treatment of Motor Disorders. The FEP Medical Policy manual can be found at: www.fepblue.org

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III. DESCRIPTION/BACKGROUND

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 but also in those with other motor disorders, such as spina bifida.

Devices used for threshold electrical stimulation are classified as "powered muscle stimulators." As a class, the U.S. Food and Drug Administration (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."

IV. RATIONALE

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 1 year previously. (1) 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 1 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 10 years, none of them demonstrating effectiveness. Dali and colleagues 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. (2) 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 1 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. (3) Fehlings and colleagues 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. (4) 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. (5)

Kerr and colleagues randomly assigned 60 children with cerebral palsy to 1 hour daily neuromuscular stimulation (n=18), overnight threshold electrical stimulation (n=20), or overnight sham stimulation (n=22). (6) 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 2 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. (7)

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Summary

The studies published to date demonstrate that threshold electrical stimulation is not effective for treatment of spasticity, muscle weakness, reduced joint mobility, or motor function; therefore the treatment is considered not medically necessary**.**

Practice Guidelines and Position Statements

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.(8)

V. DEFINITIONS

DIPLEGIA is paralysis of corresponding parts on both sides of the body.

VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. REFERENCES

1. *Steinbok P, Reiner A, Kestle JR. Therapeutic electrical stimulation (ThresholdES) following selective posterior rhizotomy in children with spastic diplegic cerebral palsy: a randomized clinical trial. Dev Med Child Neurol 1997; 39(8):515-20.*

2. *Dali C, Hansen FJ, Pedersen SA et al. Threshold electrical stimulation (TES) in ambulant children with CP: a randomized double-blind placebo-controlled clinical trial. Dev Med Child Neurol 2002; 44(6):364-9.*
3. *van der Linden ML, Hazlewood ME, Aitchison AM et al. Electrical stimulation of gluteus maximus in children with cerebral palsy: effects on gait characteristics and muscle strength. Dev Med Child Neurol 2003; 45(6):385-90.*
4. *Fehlings DL, Kirsch S, McComas A 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 2002; 44(11):741-4.*
5. *Ozer K, Chesher SP, Scheker LR. Neuromuscular electrical stimulation dynamic, bracing for the management of upper-extremity spasticity in children with cerebral palsy. Dev Med Child Neurol 2006; 48(7):559-63.*
6. *Kerr C, McDowell B, Cosgrove A et al. Electrical stimulation in cerebral palsy: a randomized controlled trial. Dev Med Child Neurol 2006; 48(11):870-6.*
7. *Lannin N, Scheinberg A, 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):533-9.*
8. *The National Institute of Neurological Disorders and Stroke. Cerebral Palsy: Hope through research. Available online at: http://www.ninds.nih.gov/disorders/cerebral_palsy/detail_cerebral_palsy.htm#179393104. Last accessed September, 2011*

Other:

Mondofacto Online Medical Dictionary. [Website]:http://www.mondofacto.com/facts/dictionary. Accessed November 13, 2012.

IX. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

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Threshold electrical stimulation as a treatment of motor disorders is consider**ed not medically necessary;** therefore the following code is not covered when used for threshold electrical stimulation as a treatment of motor disorders:

HCPCS Code	Description
E0745	Neuromuscular stimulator, electronic shock unit

X. POLICY HISTORY

MP-6.046	**CAC 10/25/11** Adopted BCBSA. Removed information regarding threshold stimulation from MP-6.020, Electrical Stimulation Modalities and created separate policy. Changed policy statement from investigational to not medically necessary.
	CAC 1/29/13 Consensus review. References updated; no change to policy statement. FEP variation added to refer to the FEP manual. Codes reviewed 11/29/12 klr
	CAC 1/28/14 Consensus review. References updated. No changes to the policy statement. Rationale added**.**

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