Regence Oregon and Utah | Regence Idaho and select counties of Washington

Medical Policy Manual

Topic: Threshold Electrical Stimulation as a Treatment of Motor Disorders

Date of Origin: July 2000

Section: Durable Medical Equipment

Last Reviewed Date: December 2013

Policy No: 83.05

Effective Date: February 1, 2014

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

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.

Regulatory Status

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.” There are currently more than 30 devices with 510(k) approval from the FDA. Marketing clearance via the 510(k) process does not require data regarding clinical efficacy.

MEDICAL POLICY CRITERIA

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

SCIENTIFIC EVIDENCE

The principal outcomes associated with treatment of motor disorders are improvements in strength, function or mobility, and minimization of pain. Outcomes relating to use of a threshold electrical stimulation device are best understood in comparison with treatment from a placebo device. Therefore, data from adequately powered, blinded, randomized controlled trials (RCT) are required to control for the placebo effect, determine its magnitude, and determine whether any treatment effect provides a significant advantage over the placebo.

Validation of therapeutic electrical stimulation also requires controlled, randomized studies that can isolate the contribution of the electrical stimulation from other components of conservative therapy such as standardized regimens of physical therapy, oral medications, and/or botulinum toxin injections.

Systematic Reviews/Technology Assessments

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 supporting their use is poor.[1] It is not clear whether electrical stimulation, as a supplement to botulinum toxin, is associated with any additional improvement in health outcomes.

Randomized Controlled Trials (RCTs)

Several RCTs have been conducted on the use of threshold electrical stimulation for treatment of motor disorders in children with cerebral palsy or types II/III spinal muscular atrophy:[2-7]

- Steinbok and colleagues conducted a randomized trial of threshold electrical stimulation.[2] Forty-four patients with spastic cerebral palsy who had undergone a selective posterior lumbosacral rhizotomy at least one year previously were randomized to receive a 12-month period of 8 to 12 hours of nightly electrical stimulation or no therapy. Results from this study should be interpreted with caution. Although the therapists who assessed outcomes were blinded to the treatment, patients and their parents were not. Lack of patient blinding introduces potential bias in favor of the electrical stimulation. Additionally, patients were encouraged to maintain the ongoing therapy in which they were participating, and the type of physical therapy in either the control or treatment group was not described. The lack of control for associated physical therapy limits interpretation of the study results.

- Dali and colleagues published the results of a double blind, placebo-controlled trial that randomized 57 children with cerebral palsy to receive either threshold electrical stimulation or a sham device for a 12-month period.[3] Visual and subjective assessments showed a trend in favor of the treatment group; however, 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.

- Three small randomized controlled studies (n <24) reported conflicting results in the study of threshold electrical stimulation as a treatment of motor disorders related to cerebral palsy or types II/III spinal muscular atrophy.[4-6] However, conclusions from these studies should be interpreted with caution due to small sample sizes.

- Finally, Kerr and colleagues compared the efficacy of neuromuscular electrical stimulation (NMES), threshold electrical stimulation and placebo in strengthening the quadriceps muscles in children with cerebral palsy.[7] Sixty children were randomized to receive sixteen weeks of therapy with NMES (n=18), threshold electrical stimulation (n=20) or placebo (n=22). At six-week follow-up, no statistically significant between-group differences were found for strength or function, although a statistically significant difference was found favoring threshold electrical stimulation on the impact of disability. Retrospective analysis indicated that the study fell short of the 110 to 190 subjects required to achieve statistical power for measures of strength and function, indicating that if any further between-group differences existed, the study was too small to find them.

Clinical Practice Guidelines

No evidence based clinical practice guideline was identified which recommend the use of threshold electrical stimulation for any type of motor disorder.

Summary

Based on the lack of published long-term objective outcomes from well-designed, well-executed randomized controlled clinical trials, conclusions cannot be reached concerning the effectiveness of threshold electrical stimulation as a treatment of motor disorders, or any other condition. Larger, randomized, placebo-controlled trials of longer duration are needed to evaluate the effectiveness of threshold electrical stimulation devices in improving strength, function or mobility, and minimizing pain and to determine whether threshold electrical stimulation offers any additional benefit compared with sham treatment or other standard treatments. Therefore, threshold electrical stimulation is considered investigational for all indications.

REFERENCES

1. 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 Jun;48(6):533-9. PMID: 16700950
2. Steinbok, P, Reiner, A, Kestle, JR. Therapeutic electrical stimulation following selective posterior rhizotomy in children with spastic diplegic cerebral palsy: a randomized clinical trial. *Dev Med Child Neurol*. 1997 Aug;39(8):515-20. PMID: 9295846
3. 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 Jun;44(6):364-9. PMID: 12088304
4. van der Linden, ML, Hazlewood, ME, Aitchison, AM, Hillman, SJ, Robb, JE. Electrical stimulation of gluteus maximus in children with cerebral palsy: effects on gait characteristics and muscle strength. *Dev Med Child Neurol*. 2003 Jun;45(6):385-90. PMID: 12785439

5. Fehlings, DL, Kirsch, S, McComas, A, Chipman, M, Campbell, K. 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 Nov;44(11):741-4. PMID: 12418614
6. Ozer, K, Chesher, SP, 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 Jul;48(7):559-63. PMID: 16780624
7. Kerr, C, McDowell, B, Cosgrove, A, Walsh, D, Bradbury, I, McDonough, S. Electrical stimulation in cerebral palsy: a randomized controlled trial. *Dev Med Child Neurol*. 2006 Nov;48(11):870-6. PMID: 17044952
8. BlueCross BlueShield Association Medical Policy Reference Manual "Threshold Electrical Stimulation as a Treatment of Motor Disorders." Policy No. 1.01.19

CROSS REFERENCES

Electrical Stimulation Devices Index, Durable Medical Equipment, Policy No. 83

CODES	NUMBER	DESCRIPTION
CPT	None	
HCPCS	E1399	Durable medical equipment, miscellaneous