Disability
Our medical policies are designed for informational purposes only and are not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

Description
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.”

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

Policy Guidelines
Threshold electrical stimulation may be associated with routine physical therapy visits over the course of the entire 12-month course of treatment. In addition, the therapy requires the rental or purchase of an electrical stimulation device, which may be coded as E0745 (neuromuscular stimulator, electronic shock unit).
Certain clinics may specialize in threshold electrical stimulation, and thus patients may request out of network referral.

Rationale
This policy was originally created in 2000 and was updated regularly with searches of the MEDLINE database. The most recent literature search was performed through September 2012. 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 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)

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)

Medicare National Coverage

There is no national coverage determination.

References:


<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td></td>
<td>No specific code</td>
</tr>
<tr>
<td>ICD-9 Procedure</td>
<td></td>
<td></td>
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<tr>
<td>ICD-9 Diagnosis</td>
<td>343.0–343.9</td>
<td>Cerebral palsy codes</td>
</tr>
<tr>
<td>HCPCS</td>
<td>E0745</td>
<td>Neuromuscular stimulator, electronic shock unit</td>
</tr>
<tr>
<td>ICD-10-CM (effective 10/1/14)</td>
<td></td>
<td>Not medically necessary for all relevant diagnoses</td>
</tr>
<tr>
<td>ICD-10-PCS (effective 10/1/14)</td>
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<td>Cerebral palsy code range</td>
</tr>
</tbody>
</table>

**Type of Service**: Durable Medical Equipment

**Place of Service**: Home

**Index**

Cerebral Palsy, Threshold Electrical Stimulation

Electrical Stimulation, Cerebral Palsy

Threshold Electrical Stimulation, Cerebral Palsy