Clinical Policy Title: Transcutaneous electrical nerve stimulators (TENS)

Clinical Policy Number: 03.02.04

Effective Date: October 1, 2015
Initial Review Date: June 17, 2015
Most Recent Review Date: July 20, 2016
Next Review Date: July 2017

Related policies:

CP# 03.03.04 Spine pain – epidural steroid injections

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Prestige Health Choice when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Prestige Health Choice’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

A. Prestige Health Choice considers the use of transcutaneous electrical nerve stimulators (TENS) to be clinically proven and, therefore, medically necessary when the following criteria are met:
   1. Painful diabetic neuropathy.
   2. Postoperative pain for no more than one month.
   3. Chronic pain syndromes, excluding back pain, not responsive to physical therapy and pharmacotherapy after two month trial of alternative methods of pain management.

B. Prestige Health Choice considers the use of Transcutaneous Electrical Nerve Stimulators (TENS) to be investigational and, therefore, NOT medically necessary for following conditions for which evidence no longer supports utilization:
   1. Chronic or acute low back pain.
   2. Migraines.
   3. Childbirth.
   4. Deep abdominal or pelvic pain.
5. All other uses of TENS not described.

Limitations:

Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website can be accessed at http://ahca.myflorida.com/Medicaid/.

All other uses of Transcutaneous Electrical Nerve Stimulators are not medically necessary.

Alternative covered services:

- Medications prescribed by treating provider
- Physical therapy program
- Epidural steroid injections
- Approved surgery

Background

Transcutaneous Electrical Nerve Stimulation (TENS) uses low level electrical currents typically from a battery-based device through surface electrodes with the goal of alleviating pain. Wall and Sweet’s sentinel observations on pain reduction in eight patients with chronic cutaneous pain was published in 1967 in Science. The first patent on a device incorporating the concepts behind TENS was obtained in 1974 by D. Maurer on the Medtronics Corporation (Patent # US3817254 A). The concept of TENS therapy is based upon the gate theories of pain. A noxious electrical current is thought to block reception in the brain of pain stimuli originating through pain fibers more distal. However there are other theories on how electrical stimulation can reduce perception of pain including: Presynaptic inhibition in the dorsal horn of the spinal cord and increase in endorphins.

The device is generally considered safe with very few in any side-effects. The medical literature has not reliably demonstrated efficacy of the therapy as it has been used for a wide variety of pain etiologies, and has not had standardization of the electrical frequency, pulse amplitude, pulse duration and physical placement locations. Many studies have not been well controlled. A number of review studies have been written with wide variation in determinations of the effectiveness of this modality. Clinical trials have been in place for a wide variety of pain from that of childbirth to low back pain to acute post-operative pain.

Most studies have suffered from low number of patients studied, failure of having adequate controls with sham TENS and by not standardizing the stimuli. Olsen et al performed a trial of high frequency versus low frequency TENS for pain management in the post-partum period. While they found that the high frequency stimulation gave better pain management control, the numbers were too low to draw
meaningful conclusions (12 in the study group and 9 in the control population). However, Limoges et al found no significant differences in pain for patients undergoing screening flexible sigmoidoscopy.

The use of TENS for patients with painful diabetic neuropathy has been found to be effective in studies by Bil et al, and such investigators as Jin, Moharić, and Forst. However there is so significant difference in pain management compared to some anticonvulsants (eg, pregabalin, gabapentin), antidepressants (eg, amitriptyline, duloxetine), opioids (eg, morphine sulfate, oxycodone), or capsaicin cream. TENS must be considered to be one of multiple options in the management of chronic pain from diabetic neuropathy.

TENS units have been found to provide pain relieve in the postoperative period. Baki et al found in a study of forty matched patients, that the use of TENS for thoracotomy patients was significant but not as complete as paravertebral block. Solak found in another study of forty matched patients who had thoracotomy, that by the third postoperative day, patients using TENS unit were more comfortable than those using patient controlled analgesics with narcotics.

However, initial enthusiasm for the use of TENS for the management of low back pain, labor, colonoscopy, headache, temporomandibular joint syndrome, or other procedures within the body cavities, have not proved to be any more successful than placebo. The clinical evidence does not support use of transcutaneous electrical stimulation for such pain syndromes.

Searches:

Prestige Health Choice searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services.

Searches were conducted on June 9, 2016, using terms “transcutaneous electrical nerve stimulator” or "TENS"

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.
Findings

Basic scientific evidence suggests that there are peripheral and central nervous system mechanisms underlying the analgesic action of TENS. Studies also show that tolerance to repeated application of TENS can be prevented by multiple strategies, both pharmacologic and nonpharmacologic. Experimental pain studies and clinical trials are beginning to refine parameters of stimulation to obtain the best pain relief. It seems that stimulation intensity is a critical factor for the effectiveness of TENS. One meta-analysis was able to show the positive treatment effects of electrical stimulation for relief of chronic musculoskeletal pain, and randomized controlled trials consistently demonstrate the effectiveness of TENS for acute, emergent, and postoperative pain conditions. However, the effectiveness of TENS on individual pain conditions, such as low back pain, is still controversial, likely because of poor study designs and small sample size. Thus, continued research of TENS mechanisms and stimulation parameters in adequately characterized patient populations is critical.

Policy updates:

None.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Abruzzi (2012)</td>
<td><strong>Key Points:</strong></td>
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<tr>
<td></td>
<td>• TENS associated with pharmacological analgesia provides pain relief compared to the placebo</td>
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<tr>
<td></td>
<td>• TENS in postoperative thoracic surgery patients both approached by thoracotomy and sternotomy. In the sternotomy it also provides more effective pain relief compared to pharmacological analgesia alone, but has no significant effect on pulmonary function.</td>
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<tr>
<td>Pieber (2010)</td>
<td><strong>Key Points:</strong></td>
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<tr>
<td></td>
<td>• Meta-analysis of studies on the use of TENS for diabetic neuropathy.</td>
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<td></td>
<td>• The studies had different conclusions and outcomes making a full determination of outcomes to be individualized.</td>
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<tr>
<td>Keller (2007)</td>
<td><strong>Key Points:</strong></td>
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<tr>
<td></td>
<td>• Comparison of multiple modalities for management of low back pain shows TENS is lowest in impact</td>
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<td></td>
<td>• For acute LBP, the effect size of non-steroidal anti-inflammatory drugs (NSAIDs) and manipulation were only modest (ES: 0.51 and 0.40, respectively) and there was no effect of exercise (ES: 0.07).</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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|          | • For chronic LBP, acupuncture, behavioral therapy, exercise therapy, and NSAIDs had the largest effect sizes (SMD: 0.61, 0.57, and 0.52, and RR: 0.61, respectively), all with only a modest effect.  
  • Transcutaneous electric nerve stimulation and manipulation had small effect sizes (SMD: 0.22 and 0.35, respectively). |
| Brosseau (2002) | **Key Points:**  
  • Meta-analysis with five trials were included, with 170 subjects randomized to the placebo group receiving sham TENS and 251 subjects receiving active TENS (153 for conventional mode, 98 for acupuncture-like TENS).  
  • The results of the meta-analysis present no evidence to support the use or nonuse of TENS alone in the treatment of chronic low back pain |

**Glossary**

**Chronic low back pain (CLBP)** — Is pain, muscle tension, or stiffness localized below the costal margin and above the inferior gluteal folds, with or without sciatica, and is defined as chronic when it persists for 12 weeks or more.

**Diabetic Neuropathy** — Damage to the peripheral nerves especially in those nerves with the greatest distance from the central nervous system. Peripheral neuropathy or diabetic neuropathy represents damage that causes pain and difficulty in position.

**Gate Control Theory** — The concept that noxious stimuli reach “nerve gates” at the spinal cord level. Pain signals can be blocked by other stimuli based upon strength and intensity of signal. The electrical impulses from TENS are felt to take advantage of gate control theory to be effective.

**Medically Necessary** — A service or benefit is Medically Necessary if it is compensable under the Medical Assistance Program and if it meets any one of the following standards:
  • The service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.  
  • The service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.  
  • The service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

**References**

**Professional society guidelines/other:**


Peer-reviewed references:


Hurlow A, Bennett MI, Robb KA, Johnson MI, Simpson KH, Oxberry SG. Transcutaneous electric nerve stimulation (TENS) for cancer pain in adults. Cochrane Database Syst Rev. 2012 Mar 14;3


7.


Clinical trials:

Searched clinicaltrials.gov on June 9, 2016 using terms transcutaneous electrical nerve stimulators Low back pain | Open Studies. Nine studies found, none relevant.

CMS National Coverage Determinations (NCDs):


not reasonable and necessary for the treatment of CLBP under section 1862(a)(1)(A) of the Social Security Act.


Local Coverage Determinations (LCDs):


**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>64550</td>
<td>Application of surface (transcutaneous) neurostimulator</td>
<td></td>
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<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>G89.18</td>
<td>Other acute postoperative pain</td>
<td></td>
</tr>
<tr>
<td>G89.21</td>
<td>Chronic pain due to trauma</td>
<td></td>
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<tr>
<td>G89.22</td>
<td>Chronic post-thoracotomy pain</td>
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<tr>
<td>G89.28</td>
<td>Other chronic postprocedural pain</td>
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<tr>
<td>G89.4</td>
<td>Chronic pain syndrome</td>
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<table>
<thead>
<tr>
<th>HCPCS Level II Code</th>
<th>Description</th>
<th>Comment</th>
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<tr>
<td>A4558</td>
<td>Conductive gel or paste, for use with electrical device (e.g., TENS, NMES), per oz</td>
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<tr>
<td>A4595</td>
<td>Electrical stimulator supplies, 2 lead, per month, (e.g. TENS, NMES)</td>
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<tr>
<td>E0720</td>
<td>Transcutaneous electrical nerve stimulation (TENS) device, 2 lead, localized stimulation</td>
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<tr>
<td>E0730</td>
<td>Transcutaneous electrical nerve stimulation (TENS) device, 4 or more leads, for multiple nerve stimulation</td>
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