
Health Technology Clinical Committee Findings and Coverage Decision

Topic: Electrical Neural Stimulation (ENS)

Meeting Date: October 30th, 2009

Final Adoption: November 20th, 2009

Number and Coverage Topic

20091030A – Electrical Neural Stimulation

HTCC Coverage Determination

Electrical Neural Stimulation is a **non-covered benefit**. This decision applies to use of durable medical equipment ENS device and supplies outside of medically supervised facility settings (e.g. in home use).

HTCC Reimbursement Determination

❖ Limitations of Coverage

- Not Applicable

❖ Non-Covered Indicators

- The use of durable medical equipment ENS device and supplies outside of medically supervised facility settings (e.g., in home use).

❖ Agency Contact Information

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

Health Technology Background

The Electrical Neural Stimulation (ENS) topic was selected and published in December 2008 to undergo an evidence review process. Pain is a very prevalent and burdensome condition. Back pain is the most commonly reported of all types with more than 25% of adults reporting low back pain in the prior 3 months, with pain most commonly reported among adults 45 years of age and over. Many treatments, increasing in number, are available to manage acute and chronic pain including physical therapies, medications, surgical intervention, neural blocks, psychotherapy, and complementary and alternative practices.

Pain is one of the most common causes of disability in the United States. Low back pain, headache, and joint pain, aching, or stiffness are among the most common complaints. Types of acute pain: procedural pain, pre-and postoperative pain, post-traumatic pain, dental procedures, and labor pain. Conditions that can lead to chronic pain: arthritis, low back pain, and other musculoskeletal problems. Transcutaneous electrical stimulation (TENS) is a commonly prescribed treatment. Estimates of use are limited, but there were 275,000 reported TENS prescriptions in 1991. Proponents estimate 50% - 80% of chronic pain patients and 6% - 44% of acute pain patients benefit from TENS. Although TENS has been widely adopted, it is unclear that benefit has been established for pain relief in high quality studies.

Treatment with TENS involves the transmission of electrical energy from an external stimulator to the peripheral nerve system via cutaneously placed conductive gel pads (electrodes). Usually have a single channel (with two electrodes) or dual channels (with four electrodes). Manner in which the current is delivered can vary in frequency, intensity, pulse width, electrode placement and duration.

In September 2009, the HTA posted a draft and then followed with a final report from a contracted research organization that reviewed publicly submitted information; searched, summarized, and evaluated trials, articles, and other evidence about the topic. The comprehensive, public and peer reviewed, Electrical Neural Stimulation report is 102 pages, and identified a relatively large amount of literature.

An independent group of eleven clinicians who practice medicine locally meet in public to decide whether state agencies should pay for the health technology based on whether the evidence report and other presented information shows it is safe, effective and has value. The committee met on October 30th, reviewed the report, including peer and public feedback, and heard agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at <http://www.hta.hca.wa.gov> under the committee section.

The Draft Findings and Decision was posted to the HTA website for public comment. The HTCC met on November 20th, and having reviewed public comments, adopted this findings and decision document, with editorial corrections.

Committee Findings

Having considered the evidence based technology assessment report and the written and oral comments, the committee identified the following key factors and health outcomes, and evidence related to those health outcomes and key factors:

1. Evidence availability and technology features

The committee concludes that the best available evidence on electrical neural stimulation has been collected and summarized.

- ENS devices use electrical stimulation of nerves via pads on the skin. However, ENS topics is made difficult to assess by the wide variance in different devices, differing placement locations, and delivering varying pulse, and frequency of stimulation, and duration at each treatment and over time. Cochrane reviews included different modalities in their reports which were grouped by different clinical indications.
- Electrical neural stimulation (ENS) is a commonly prescribed treatment that has been in use for over 30 years, is widely used and adopted despite unclear benefit.
- Evidence from eight Cochrane reports reviewing 86 randomized controlled trials and six additional randomized, controlled trials, provides a relatively large evidence base consisting of randomized trials, but the evidence is mostly insufficient, low quality data providing mixed results on a generally narrow outcome of short term pain relief.
- Given the variety of device types and conditions, the committee sought to focus discussion and consideration. The data from agencies on cost was associated with durable medical equipment purchase or rental of ENS devices and supplies, and CMS' policy was similar. Agency comments indicated that charges for use in facility are included in overall charges, not generally separable and managed through daily or unit caps the apply to broad group of services. The committee decided to limit deliberation and decision(s) to ENS prescribed for take home or outside clinic setting and excluded further consideration of ENS used as part of a clinician's in facility services (e.g. use in labor or use in physical therapy facility).

2. Is the technology safe?

The committee concludes that the comprehensive evidence reviewed shows that the ENS technology is safe. Key factors to the committee's conclusion included:

- The committee agreed with the evidence report conclusions that indicated ENS is not associated with mortality.
- The evidence report concludes that most adverse effects were mild, most often associated with irritation at the electrode site or discomfort with the sensation of TENS current. No significant adverse outcomes identified, though studies may be underpowered for this event, the ENS devices are used to deliver small currents to the skin and no significant adverse complications would be expected.
- The devices have been in wide use for 30 years with no observed effects. A small issue for in home use and the possible unknown effect (long term) of over stimulation of nerve fibers was raised, but agreed unlikely.

3. Is the technology effective?

The committee concludes that the comprehensive evidence reviewed shows that TENS is not more effective for treatment of acute or chronic pain. Note: consistent with overall decision, this conclusion applies to use of durable medical equipment ENS device and supplies outside of medically supervised facility settings (e.g. in home use).

- Overall, the committee agreed with the evidence based report that concluded, despite identification a over 80 randomized trials, the evidence is insufficient for evidence based conclusions about efficacy or effectiveness of ENS due to mostly low or very low quality studies (small numbers, lack of blinding, intermediate or insufficient outcomes, variable devices, indications and settings used, inadequate descriptions and controls, and measurements, conflicting results), though some indications and devices have somewhat higher quality evidence.
- The committee reviewed findings primarily for the chronic pain, low back, and knee osteoarthritis indications as these were noted as primary uses by agencies and/or had relatively higher levels of evidence (either quantity or design).
- No reliable information was available on important outcomes of reduction in analgesic medication, improvement in functional status, or quality of life.
- Pain – the primary outcome measured generally focused on short term outcomes with no evidence on long term use or outcomes although primary state costs and usage are for longer term. Low quality is insufficient to conclude whether ENS treatment provides or does not provide benefit. If any benefit demonstrated, evidence is limited by short term trial duration/follow up.
- While there was broad agreement on lack of evidence of benefit, the clinical issue of the value of a placebo effect for some patients who may then not need treatment with medication (generally opioids) where there are known risks and costs was discussed. There is no current evidence that ENS usage eliminates or reduces medication use, but this was not evaluated and clinical experience indicates it may effect decision making. A related factor discussed was that the issue was payment, not ability to access (many items such as specialized mattresses or pillows available to try but not insured benefit), and the in clinic treatment is not under consideration.
- The committee discussed the issue of comparators, ultimately deciding on treatment with ENS versus treatment without ENS.

4. Is the technology cost-effective?

The committee concludes that the comprehensive evidence review shows no published good quality evidence on ENS treatment.

- Committee noted that where efficacy and effectiveness are not established, cost effectiveness is premature. No quality studies have been produced, and the one included cost savings estimate is based on assumptions of decreased medication and physical therapy use, neither of which have been studied, reported on or demonstrated.
- Committee acknowledged the state agency costs of nearly \$3million over last four years, generally increasing and reaching nearly 1 million last year (900,000) in the durable medical equipment (DMS) costs.

5. Medicare Decision and Expert Treatment Guidelines

Committee reviewed and discussed the Medicare coverage decision and expert guidelines as identified and reported in the technology assessment report.

- Centers for Medicare and Medicaid Services (2003) – CMS will cover the use of TENS for the relief of acute post-operative pain. TENS may be covered whether used as an adjunct to the use of drugs, or as an alternative to drugs. TENS devices, whether durable or disposable, may be used in furnishing this service. In cases where TENS is used for longer than 30 days, TENS may be covered as durable medical equipment (DME). PNT only covered if performed by a physician. No evidence cited for these decisions.
- Guidelines – a search of the National Guideline Clearinghouse (NGC) returned 8 potential guidelines on the use of TENS for pain management. Of those, 6 specifically described conditions for TENS use and provide specific recommendations. In general, very little information specific to the use of TENS with regard to chronic conditions like low back pain, rheumatoid arthritis, headache, and neuropathic pain were described. Two guidelines that described management of acute pain conditions, concluded that TENS therapy was generally not recommended. The following provides a summary of the guidelines that were most relevant:
 - (1) University of Iowa Gerontological Nursing Interventions Research Center, Research Translation and Dissemination Core – good evidence that TENS can be used as a non-pharmacological, physical method for the treatment of persistent pain in older adults; although, other therapies have been found to be useful, the evidence is still preliminary and inconclusive.
 - (2) American College of Occupational and Environmental Medicine (ACOEM) – the only recommendation was TENS therapy for low back pain; however, the evidence was described as limited and it was only recommended for select appropriate patients. All other ENS modalities were not recommended or described.
 - (3) Ottawa Panel evidence-based practice guidelines on electrotherapy for the management of rheumatoid arthritis – overall, only low frequency TENS applied to the hand and wrist showed a small clinical benefit.
 - (4) Institute for Clinical Systems Improvement (ICSI) – TENS units for migraine or muscle contraction headache have not been found to be more beneficial than placebo when evaluated in a controlled study.
 - (5) National Headache Foundation – Considering the inconvenience and the limited efficacy, this treatment was not recommended.
 - (6) European Federation of Neurological Societies (EFNS) – they concluded standard high-frequency TENS might be better than placebo.
 - (7) Stoke Rehabilitation Clinical Practice Guidelines – this guideline does not address the use of TENS for pain relief specifically, but describes TENS for decrease in spasticity, and increase in functional status (motor function, gait speed, passive shoulder range of motion, and sensation).
 - (8) American Pain Society – concluded there was insufficient evidence to accurately judge the efficacy of TENS versus other interventions for chronic low back pain or for acute low back pain. In a more recent guideline, TENS was not listed as an interventional therapy for patients with low back pain.

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, agency and state utilization information. The committee concluded that the current evidence on Electrical Neural Stimulation demonstrates that there is insufficient evidence to cover the use of Electrical Neural Stimulation. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. The committee found that Electrical Neural Stimulation didn't have a mortality rate; morbidity from ENS was unusual and generally mild, most often associated with irritation at the electrode site or discomfort with the sensation of ENS current; and ENS showed insufficient evidence to conclude it was effective in reducing pain, increasing patient satisfaction and reducing analgesic consumption.

Based on these findings, the committee voted 8 to 2 to not cover Electrical Neural Stimulation for durable medical equipment usage (buying or renting the equipment for home use).

Health Technology Clinical Committee Authority

Washington State's legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to gather and assess the quality of the latest medical evidence using a scientific research company and take public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State Health Technology Clinical Committee (HTCC), determines how selected health technologies are covered by several state agencies. RCW 70.14.080-140. These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. Selected technologies are considered for re-review on the basis of new evidence.