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**Health Technology Clinical Committee**
**Date: October 30<sup>th</sup>, 2009**
**Time: 8:00 am – 5:00 pm**
**Location: Marriott Hotel – 3201 South 176<sup>th</sup> Street, Seattle, WA 98188**
**Teleconference Bridge: 1-360-923-2997 Access Code: 360-946-1464**
**Adopted: November 20<sup>th</sup>, 2009**

## HTCC MINUTES

**Members Present:** Brian Budenholzer; Michael Myint; Carson Odegard; Michael Souter; C. Craige Blackmore; Louise Kaplan; Megan Morris and Christopher Standaert; Michelle Simon; and Richard Phillips.

Members Absent: Jay Klarnett

### HTCC FORMAL ACTION

1. **Call to Order:** Dr. Budenholzer, Chair, called the meeting to order. Sufficient members were present to constitute a quorum.
2. **August 28<sup>th</sup>, 2009 Meeting Minutes:** Chair referred members to the draft minutes; motion to approve and second, discussion ensued.
  - *Action: Nine committee members approved the August 28<sup>th</sup>, 2009 meeting minutes. One committee member abstained since she wasn't present at the August meeting.*
3. **Vagal Nerve Stimulation for Epilepsy and Depression draft Findings & Decision:** Chair referred members to the draft findings and decision and called for further discussion or objection. The Vagal Nerve Stimulation findings & decision was approved and adopted by the committee.
  - *Action: Nine committee members approved the Vagal Nerve Stimulation findings & decision document. One committee member abstained from voting since they were not present at the previous clinical committee public meeting.*
4. **Bone Growth Stimulation draft Findings & Decision:**

Chair referred members to the draft findings and decision and called for further discussion or objection. The Bone Growth Stimulation findings and decision was approved and adopted by the committee. Final approval was subject to updating the document to include the entire Medicare guideline.

  - *Action: Nine committee members approved the Bone Growth Stimulator findings & decision document. One committee member abstained from voting since they were not present at the previous clinical committee public meeting.*
5. **Electrical Neural Stimulation:** The HTCC reviewed and considered Electrical Neural Stimulation technology assessment report; information provided by the Administrator; state agencies; public members; and heard comments from the evidence reviewer, HTA

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program, and agency medical directors. 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. 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 COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	Covered Unconditionally	Covered Under Certain Conditions
Electrical Neural Stimulation	8	0	2

- *Action:* The committee chair directed HTA staff to prepare a Findings and Decision document on Electrical Neural Stimulation reflective of the majority vote

6. **Cardiac Stents:** The ad hoc advisory reported back their findings to the committee based on a previous motion from the August 28<sup>th</sup> public meeting to convene an ad hoc advisory group to provide expert input on potential additional groups at high risk of restenosis and any evidence supporting. 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 updated the limitations of coverage for Cardiac Stents.

HTCC COMMITTEE COVERAGE DETERMINATION VOTE			
	Not covered	Covered Unconditionally	Covered Under Certain Conditions
Cardiac Stents	0	1	9

- The committee reviewed the findings and decision, and amended the limitations of coverage to read as follows:

- Limitations of Coverage:

- Bare Metal Stents are covered without conditions
- Drug eluting stents are conditionally covered for:
  1. Stent diameter of 3 mm or less;
  2. Length of stent(s) of longer than 15 mm placed within a single vessel;
  3. Patients with diabetes mellitus;
  4. Stents placed to treat in stent restenosis; or
  5. Treatment of left main coronary disease.

- *Action:* Ten committee members approved the Findings and Decision document, as amended to reflect the limitations above and notation of the input and report from an ad hoc workgroup.



## **SUMMARY OF HTCC MEETING TOPICS, PRESENTATION, AND DISCUSSION**

### **Agenda Item: Welcome & Introductions**

- ✓ The Health Technology Clinical Committee (HTCC) met on October 30<sup>th</sup>, 2009.

### **Agenda Item: Meeting Open and HTA Program Update**

Dr. Brian Budenholzer, HTCC Chair, opened the public meeting. Leah Hole-Curry, HTA Program Director, provided an overview of the agenda, meeting guide and purpose, room logistics, and introductions.

Leah Hole-Curry, HTA Program Director, provided an update on HTA program activities and outcomes.

- ✓ Evidence Reports Underway: Calcium Scoring, Hip Resurfacing, Glucose Monitoring and Sleep Apnea Diagnosis and Treatment are currently underway with the vendor and the HTA program.
- ✓ Staffing Changes: Margaret Dennis has been hired as the HTA program manager and the contract for program clinical consultant has expired. The program is reviewing alternatives for this role.
- ✓ 2010 Potential Topic Selection: The potential list for 2010 is published on our HTA website and is accepting public comment until November 10<sup>th</sup>, 2009. Once all public comments have been gathered, the HCA Administrator will review and make the final selection for 2010. Potential topics include: kyphoplasty / sacroplasty / vertebroplasty; hyaluronic acid injections; spinal injections; MRI for breast cancer; CT / MRI for abdomen / pelvis; spinal cord stimulation; ABA therapy for autism; routine ultrasound for pregnancy; knee replacement and prostate specific antigen testing.

### **Agenda Item: Previous Meeting Business**

August 28<sup>th</sup>, 2009 Meeting Minutes: Chair referred members to the draft minutes and called for a motion and discussion. Minutes were circulated prior to the meeting and posted. No committee requests for changes were received.

- *Action: Nine committee members approved the August 28<sup>th</sup>, 2009 meeting minutes. One committee member abstained since she wasn't present at the August meeting.*

Vagal Nerve Stimulation Findings and Decision: Chair referred members to the draft findings and decision and called for further discussion. The draft findings and decision document was circulated prior to the meeting and posted to the website for a two week comment period. No committee requests for changes and no public comments were received.

- *Action: Nine committee members approved the Vagal Nerve Stimulation findings & decision document. One committee member abstained from voting since she was not present at the previous clinical committee public meeting.*

Bone Growth Stimulation Findings and Decision: Chair referred members to the draft findings and decision and called for further discussion or objection. The draft findings and decision document was circulated prior to the meeting and posted to the website for a two week comment period. No committee requests for changes were received. One manufacturer and nine provider comments encouraging coverage for non-union, delayed union, and fresh fractures were received and noting that one of the CMS national coverage indications had been omitted. A second draft findings and

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decision document including all CMS coverage indications in the limitations of coverage was included in meeting package for consideration. If the second version is adopted, a conforming change to all parts of the document should be made to ensure consistency in reference to CMS coverage indications.

- *Action: Nine committee members approved the updated Bone Growth Stimulation findings & decision document, as updated to ensure consistent references to CMS coverage throughout the document. One committee member abstained from voting since she was not present at the previous clinical committee public meeting.*

### **Agenda Item: Cardiac Stents Ad Hoc Advisory Report and Committee Decision**

Cardiac Stents: Chair referred members to the ad hoc advisory group report and called for staff update and report from the clinical chair of an ad hoc advisory committee.

- ✓ **Background and staff report:** the HTCC met on May 8, 2009 to review the topic of bare metal versus drug eluting cardiac stents. The committee made a draft decision to cover bare metal stents, and cover drug eluting stents under certain conditions. The draft conditions are: cover for patients at high risk of restenosis, including patients with – diabetes, vessels smaller than 3 mm, or lesions longer than 15 mm.
- ✓ Committee Discussion - Majority of committee members concluded that:
  - The record is clear that evidence from multiple RCTs and registry studies that mortality and acute MI rates are not different between DES and BMS
  - There is a benefit to DES in that target vessel revascularization/target lesion revascularization rates are reduced by an average of 11%
  - This benefit was not large enough to outweigh the significant cost for all populations, but groups at high risk of restenosis may benefit the most from DES.
  - Groups at high risk of restenosis are not definitively established. The committee adopted the broadest definition, among other entities that had established restrictions.
- ✓ HTCC Decision to request Advisory Group: Upon circulation of the draft findings and decision, comments were received from a committee member and provider and professional groups expressing concerns or disagreement with the draft decision. At the August 28<sup>th</sup> HTCC public meeting, the clinical committee reviewed the draft findings and decision and public comments. Based on public input and committee discussion, the committee would like additional expert input prior to finalizing the conditional coverage criteria to ensure that additional high risk groups were not inadvertently left out.
- ✓ Ad Hoc Advisory Group Scope and Role: Participate in a group of technical experts to identify groups at high risk of restenosis and the evidence supporting it that are not currently included in the draft criteria. Approve a report to the HTCC, in time for distribution prior to the October 30, 2009 scheduled meeting. Subject to discussion within the group, provide report or testimony to the HTCC. Two HTCC members; a hospital association and agency representative; the evidence vendor and four cardiologists formed the workgroup. The workgroup met publicly, twice - on October 5<sup>th</sup> and 16<sup>th</sup> and selected Dr. Mike Ring to serve as the clinical chair. The workgroup started with a review of the task and a discussion of the potential high risk categories that were included in public comment. The list was updated based on comments, and members submitted some articles and other information to a central repository; reviewed the information; and eventually provided a ranking from 0 to 10 of importance of certain risk categories. After

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second discussion, a report was produced summarizing the categories and rankings by the workgroup members.

- ✓ The ad hoc advisory group report: via the clinical chair Dr. Mike Ring and with added comments by members that were present reported back their findings to the committee. The full ad hoc report is incorporated here by reference and available on the HTA website. In summary, eight additional high risk categories were included and ranked, and two changes to the language of the current criteria were recommended.
  - Additional criteria considered: TVR for in-stent restenosis; left main coronary; bifurcation lesion; chronic total occlusion; saphenous vein graft; ostial lesions and STEMI. Individual rankings were based on the evidence reviewed and the clinical judgment and experience of the members. Averaged rankings for all members and for cardiologists were included along with primary considerations.
  - Current criteria for vessel and lesion sizes were recommended to be changed to stent sizes: (1) less than 3 mm vessel was recommended to be changed to – Equal or less than 3.0 mm stent; and (2) greater than 15 mm lesion should be changed to greater than 15 mm of total stent placed within vessel.

### **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 and input from an ad hoc advisory group. The committee concluded that the current evidence on drug eluting and bare metal stents supports the previous findings and decision, with the following amendments.

- ✓ 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 updated the limitations of coverage for Cardiac Stents.
  - *Action: Ten committee members approved the Cardiac Stent findings & decision document, as updated to reflect the limitations of coverage adopted below and a reference to the inclusion and consideration of the ad hoc advisory group report.*
  - *Limitations of Coverage:*
    - *Bare Metal Stents are covered without conditions*
    - *Drug eluting stents are conditionally covered for:*
      - *Stent diameter of 3 mm or less;*
      - *Length of stent(s) of longer than 15 mm placed within a single vessel;*
      - *Patients with diabetes mellitus;*
      - *Stents placed to treat in stent restenosis; or*
      - *Treatment of left main coronary disease*

### **Agenda Item: Electrical Neural Stimulation Topic Review**

Leah Hole-Curry, HTA Program Director, introduced the technology topic up for discussion:

- ✓ Electrical Neural Stimulation: review of the evidence of the safety, efficacy and cost-effectiveness of Electrical Neural Stimulation.

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**Electrical Neural Stimulation –**

- ✓ Electrical Neural stimulation or ENS for treatment of pain was a selected 2008 topic. 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.
- ✓ Prioritization Criteria Review
  - Safety concern: Low - non-invasive little risk concern;
  - High Efficacy concern: Primary concern: low quality evidence currently available for most uses; adjunct treatment confounds results; patient selection and stimulation parameters unclear; patient compliance problematic.
  - Cost Concern: Low - Cost concerns reflect mainly concern about over or mis-utilization; expansion to added treatment areas, and long term use with rental device cost
- ✓ Medicare Coverage and Clinical Guidelines:
  - There is a National Medicare policy on ENS --
    - (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 is then considered used for chronic pain, in which case the device may be covered as durable medical equipment.
    - PNT only covered if performed by a physician.
  - ENS Clinical Guidelines – 8 guidelines identified by evidence center; six cited evidence:
    - Insufficient evidence or non-recommended: American Pain Society (acute and chronic low back); European Federation of Neurological Society (Neuropathic Pain); National Headache Foundation (Headache); Institute of Clinical System Improvement (Headache); and Ottawa Panel (Arthritis) – insufficient except wrist/hand small benefit.
    - Recommended or Evidence Supports: American College of Occupational and Environmental Medicine (selected low back conditions); University of Iowa Gerontological Nursing Intervention (low back and knee); and Stroke Rehabilitation (not pain related – spasticity relief).

**Agenda Item: Public Comments**

The Chair called for public comments.



- ✓ Scheduled Public Comments: No stakeholder requested scheduled time for public comments.
- ✓ Open Public Comments: No individuals signed up or responded to a call for public comments at the meeting.

**Agenda Item: Electrical Neural Stimulation Topic – Agency Data**

Dr. Gary Franklin, Department of Labor & Industries (LNI), Medical Director, presented to the committee the agency utilization and outcomes for Electrical Neural Stimulation.

- ✓ Originally introduced by Rx of neural pain on basis of Melzack / Wall theory of spinal pain modulation.
- ✓ Use of technology has spread primarily to non-neural pain (e.g. chronic low back pain) – questionable theoretical basis for these uses.
- ✓ Agency concerns: does it work? Evidence leaves many questions, though TENS has been used and studied for more than 30 years. If it works to relieve chronic pain – for how long? Is there improvement to function?
- ✓ Value: Costs are cumulative and related to ongoing rental / purchase of equipment and disposable accessories (e.g. leads, skin patches, custom garments with built in electrodes, etc).
- ✓ FDA approved for marketing\* for: Tx of pain and Tx of pain caused by osteoarthritis (\* = approval process - 510(k) - does not require demonstration of efficacy).
- ✓ Updated Cochrane Review: update to review addressing OA of the knee (Rutjes et al., 2009) concludes: “we could not confirm that Transcutaneous Electrostimulation is effective for pain relief. The current systematic review is inconclusive, hampered by the inclusion of only small trials of questionable quality. Appropriately designed trials of adequate power are warranted.”
  - Findings for OA knee include: 0% difference in pain improvement when using electrostimulation compared to fake electrostimulation. 3% more patients treated with electrostimulation had improved physical function compared to fake electrostimulation.
- ✓ Current Agency Policies:
  - DSHS / UMP: No coverage policy. Use Hayes.
  - L&I coverage policy: TENS and inferential units / supplies are covered for symptomatic relief and management of: chronic intractable pain, and as adjunctive treatment for post-surgical and post-trauma acute pain.
    - L&I coverage through one contracted DME provider.

**Number of Devices Rented / Purchased Per Year**

UMP, Medicaid & L&I

HCPCS CODES	2005	2006	2007	2008	Total
E0720 (TENS, 2 lead)	4	15	47	29	95
E0730 (TENS, 4 lead)	5,336	6,676	7,485	8,982	28,479
<b>Total</b>	<b>5,340</b>	<b>6,691</b>	<b>7,532</b>	<b>9,011</b>	<b>28,574</b>

\*Includes multiple instances, such as rental units

\*\*Code E0720 is not covered by L&I



**Distinct Patient Counts by Year**

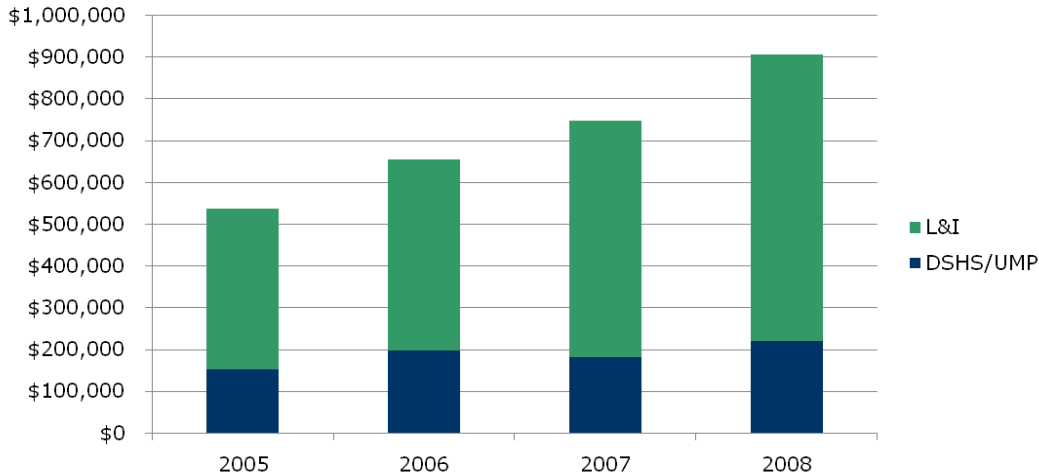
UMP, Medicaid & L&I\*

HCPCS CODES	2005	2006	2007	2008
E0720 (TENS, 2 lead)	3	7	26	18
E0730 (TENS, 4 lead)	1,792	2,163	2,661	2,998
<b>Total</b>	<b>1,795</b>	<b>2,170</b>	<b>2,687</b>	<b>3,016</b>

**Total\* Payments for Electrical Nerve Stimulation**

UMP, Medicaid & L&I

	2005	2006	2007	2008	Total
<b>Total</b>	<b>\$537,852</b>	<b>\$655,163</b>	<b>\$748,314</b>	<b>\$907,229</b>	<b>\$2,848,558</b>



- ✓ Utilization Summary: Per patient costs relatively stable; recent trend upward in total expenditures; some claim experience shows extended rental periods (many months); and increase appears due to more injured workers receiving TENS treatment.
- ✓ Agency Recommendations:
  - Non-coverage for most conditions.
  - If committee finds evidence suggestive of benefit, allow only with monitoring of pain and function.
    - Limit to 3 month time period with extension only based on demonstrated improvement during initial treatment period.

**Agenda Item: Evidence Review Presentation**

Spectrum Research presented an overview of their evidence report on Electrical Neural Stimulation.



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- ✓ Background: 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.
  - ✓ Inclusion Criteria: Cochrane reviews – previously published Cochrane reviews on the use of ENS for the treatment of acute or chronic pain (in adult populations) form the basis of this of this HTA. Included: TENS and other non-invasive forms of ENS; Interferential (IFC) therapy (also called diadynamic); and Percutaneous Neuromodulation therapy (PNT).
    - Excluded: percutaneous electrical nerve stimulation (PENS), acupuncture / electroacupuncture, spinal cord stimulation, deep brain stimulation.
  - ✓ RCTs that assessed ENS via comparison with placebo (sham), control, or other treatments provide the focus for new evidence since publication of the Cochrane reviews.
  - ✓ Literature Search: electronic databases and HTA sites searched up through August 2009 using a systematic approach; 4 previous health technology assessments or similar reports; 11 Cochrane reviews; and 1,676 potentially relevant recent RCTs.
  - ✓ Interventions: 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.
    - Conventional (high frequency) TENS generally 25 – 150 Hz (or pulses / second) in frequency and 1 – 2 mA in amplitude (or intensity). Patient feels constant tingling / prickling sensation, sometimes even numbness.
    - Acupuncture-like (low frequency) TENS generally 1 – 10 Hz in frequency and 15 – 20 mA in intensity. Intensity set close to tolerance limit of patient, leading to muscle contraction that is usually less comfortable for patient.
    - Pulse duration (width) set anywhere from 10 – 1000  $\mu$ sec – generally shorter for conventional TENS (e.g., 40 – 75  $\mu$ sec) than for acupuncture-like TENS (ALTENS; e.g., 150 – 250  $\mu$ sec).
    - Electrode placement usually at the site of pain, but other locations (e.g., over cutaneous nerves, trigger points, acupuncture sites) are commonly used as well.
    - With respect to duration, TENS can be used for single sessions or multiple sessions, over a short period of time or a long period of time, with varying durations of individual sessions.

- ✓ Comparators included: placebo (sham) TENS; control (no treatment / routine care); pharmacologic interventions; non-pharmacologic interventions; other standard forms of non-invasive ENS. Excluded: Invasive treatments (PENS, acupuncture, spinal cord stimulators, deep brain stimulation).
- ✓ Pain Scales –
  - Visual Analog Scale (VAS): commonly a series of lines 100 mm in length, with the left and right ends labeled ‘no pain’ and ‘worse pain possible’; alternatively, they can be labeled ‘no pain relief’ and ‘complete relief of pain’.
  - Verbal Numerical Scale: correlates well with 100 mm VAS scores; 0 corresponds to ‘no pain’ and 10 to ‘maximum pain possible’; alternatively, they can correspond to ‘no relief’ and ‘complete relief’.
- ✓ Key Question #1 -- Summary of Findings for Efficacy and Effectiveness for:
  - *Acute Pain* –
    - Included 12 studies, 6 of which had sufficient extractable data. Pain associated with medical procedures (e.g., Sigmoidoscopy), hemophiliac pain, acute trauma (e.g., sprains or fractures), postpartum contraction, acute oro-fascial pain, post thoracotomy, rib fractures, and neuropathic pain. Statistically significant benefit for acute pain in only two studies: after two weeks of treatment of TENS vs. placebo (N=50) and when high amplitude TENS was compared to low amplitude control (N=20).
    - Cochrane review authors concluded that definitive conclusions about the effectiveness of TENS as a treatment for acute pain in adults cannot be made.
    - Overall Strength of Evidence = Low
  - *Labor Pain* –
    - Pain Relief: severe labor pain was reduced in two studies (N=190) of TENS applied to acupuncture points. Recent RCT did not observe a significant difference between TENS vs. sham (applied to back). Patient Satisfaction: significantly more women reported satisfaction with labor pain relief compared to sham, whether applied to back or acupuncture points (5 studies, N=673). Cochrane review authors concluded that there is only limited evidence that TENS reduces pain during labor.
    - Overall Strength of Evidence = Moderate
  - *Dysmenorrhea* –
    - Pain Relief: more women reported relief of dysmenorrhea with HFTENS vs. sham when measured categorically (2 studies, N=106) or using VAS (1 study, N=18); not observed for LFTENS (4 studies). Analgesic Consumption: there was not a significant difference in dysmenorrhea between HFTENS and sham, except in a small study (N=24) reporting number of analgesic tablets taken. Cochrane review authors concluded that HFTENS was effective for the treatment of dysmenorrhea in a number of small trials, but evidence was insufficient to determine the effectiveness of LFTENS.
    - Overall Strength of Evidence = Low
  - *Chronic Pain* –
    - Included 25 studies (N=1281); did not present individual-study level data.

- Pain associated with rheumatoid arthritis, osteoarthritis, pancreatitis, myofascial pain, diabetic neuropathy, and low back pain. Patients treated with TENS were more likely to report overall positive effects with treatment for chronic pain when compared to sham within the first week, but this advantage decreased over time (average 4 weeks follow-up; only 3 studies long-term). Three of 7 studies looking at multiple dose treatments reported active TENS to be favored over sham. Cochrane review authors concluded that published literature lacks the methodological vigor or robust reporting to make confident assessments of the role of TENS in treatment of chronic pain.
    - Overall Strength of Evidence = Moderate
  - *Osteoarthritis of the Knee –*
    - Statistically significant reductions in knee pain with TENS treatment compared to sham (6 studies, N=254). Patients treated with TENS were four times as likely to report improvements in knee pain immediately after treatment (5 studies, N=214) and during follow-up (2 studies, N=62) when compared to sham. In subgroup analysis, knee pain improvement was statistically significant in high quality studies, studies of repeated TENS application, and studies with treatment durations of at least 4 weeks.
    - Greater improvement knee stiffness, quadriceps muscle strength, 50ft walking time, knee flexion for ALTENS (N=50) and knee stiffness TENS / ALTENS (2 studies, N=90). Cochrane review authors concluded that TENS and ALTENS are effective in pain control over placebo; still more well designed studies with standard protocols and adequate sample sizes are needed.
    - Overall Strength of Evidence = Moderate
  - *Chronic Low Back Pain –*
    - Cochrane review included 4 studies (N=585) and two small recent RCTs were identified; sample sizes in most studies were small. Only one study reported statistically significant pain relief with TENS use when compared to placebo. Cochrane review authors concluded that evidence from the small number of placebo-controlled trials does not support the use of TENS in the routine management of chronic low back pain.
    - Overall Strength of Evidence = Low
  - *Rheumatoid Arthritis in the Hand –*
    - Cochrane review identified 3 small studies that were too heterogeneous with respect to TENS treatment (type, treatment schedule) to allow for meta-analysis. Results were mixed – one study showing a statistically significant improvement in pain when compared to placebo but the other two did not. Muscle power and work scores were not statistically different between ALTENS and placebo after 3 weeks of treatment in a single study (N=32).
    - Overall Strength of Evidence = Very Low
  - *Neck Disorders –*
    - Cochrane Review included 5 studies that looked at TENS and 1 that looked at interferential current therapy compared with use of a cervical collar; two studies excluded because TENS included in combination with other therapies. Only one study (N=38) reported greater reduction in pain intensity with TENS treatment applied in a

- 
- single 20-minute session compared to placebo. Cochrane Review authors concluded that definitive statements on electrotherapy for mechanical neck disorders could not be made due to lacking, limited, and conflicting evidence
- Overall Strength of Evidence = Low
  - *Post-Stroke Shoulder Pain* –
    - Cochrane Review included 4 studies that compared TENS, functional electrical stimulation and HFTENS with placebo or control; only two of these studies assessed pain relief. Results were mixed; patients treated with electrical stimulation had lower pain scores in one study than control, but those treated with TENS did not. Two studies reported benefits for passive humeral lateral rotation with treatment by TENS (N=40) and functional electrical stimulation (N=26). Cochrane Review authors concluded that the evidence from RCTs does not confirm or refute that electrical stimulation around the shoulder after stroke influences reports of pain
    - Overall Strength of Evidence = Very Low
  - *Cancer Pain* –
    - Cochrane Review included only 2 small studies of TENS effect on cancer pain. No statistically significant differences were observed between TENS and control groups. Cochrane Review authors concluded that the results are inconclusive due to a lack of suitable RCTs.
    - Overall Strength of Evidence = Very Low
  - ✓ Key Question 2: Safety Summary –
    - TENS is generally regarded as safe. Other than minor skin irritation (burning, tingling, or discomfort) at the electrode site, no major adverse effects reported. Unclear how much of this is due to under-reporting, but given the non-invasiveness of the treatment, one would expect the risk of adverse effects to be low.
      - Overall Strength of Evidence = Low
  - ✓ Key Question 3: Summary of Economic Analysis –
    - None of the previously reported HTAs contained formal economic analyses specific to TENS. No full economic analyses were found in the published peer-reviewed literature. This information only represents cost information, however, and does not inform on cost-effectiveness.
    - There is insufficient evidence from one costing study on chronic pain in which simulated cost savings estimates for medications over 12 months ranged from \$240-\$560 (in 1994) US Dollars per patient and \$1052 assuming 12 PT/OT visits in 6 months.
      - Based on interview of patients via telephone – patients selected by Empi, who funded the study
      - Overall Strength of Evidence = Very Low
  - ✓ What We Know: Summary

Condition	SoE	Issues/Limitations	Conclusions
Acute Pain	Low	Small number studies, heterogeneity intervention and outcome.	Cannot draw conclusions.
Labor Pain	Moderate	Small number studies of pain severity, inconsistent results.	Limited evidence that TENS applied to acupoints may be effective; patients treated with TENS reported higher satisfaction.
Primary Dysmenorrhea	Low	Small N's, inconsistent results (particularly LFTENS).	Evidence HFTENS reduces pain in small number studies; but insufficient data for LFTENS.
Condition	SoE	Issues/Limitations	Conclusions
Chronic Pain	Moderate	Based on number and quality of studies; however, numerical data not presented and consistency across studies not explicit.	Pain relief improved with TENS use within 1 week of treatment, but decreased over time.
OA of the Knee	Moderate	Small N's; reduced heterogeneity allowed for meta-analysis.	TENS was found to be superior to placebo, with the difference both statistically significant and clinically important (particularly immediately following treatment).  Single study suggests that PNT is more effective than placebo, but only immediately following therapy.
Chronic LBP	Low	Small number of studies, small N's.	Only a single study indicated benefit with TENS; cannot draw conclusions.
Condition	SoE	Issues/Limitations	Conclusions
RA in the Hand	Very Low	Small number of studies, heterogeneous; mixed results.	Only 1 of 3 studies showed improvement; cannot draw conclusions.
Neck Disorders	Low	Small number of studies, heterogeneous, mixed results.	Cannot draw conclusions.
Post-Stroke Shoulder Pain	Very Low	Small number of studies; mixed results.	No conclusions can be drawn on pain improvement; TENS may improve functional outcome of PHLR.
Cancer Pain	Very Low	Small number of studies, small N's.	No differences were observed, but conclusions cannot be drawn from these two studies.

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- ✓ Remaining Questions: Although the primary evidence in this assessment comes from Cochrane Reviews, meta-analyses were not appropriate for most of the data given the heterogeneity in study populations, intervention characteristics, and outcome measures.
  - For many of the outcomes, there were a small number of studies, with small sample sizes. Additionally, even many of the well-designed studies only applied TENS in a single session or for a short duration.
  - These limitations preclude the drawing of concrete conclusions. More evidence is needed to support or reject TENS as an effective treatment for acute and chronic pain.
- ✓ Systematic Review Search Results: Eight Cochrane Reviews that included 86 studies. Search found N=1676 articles → N=1668 Excluded at Abstract → N=9 Full Article Review → N=6 Included → N=3 Excluded.

### **Agenda Item: HTCC Electrical Neural Stimulation Discussion and Findings**

Brian Budenholzer, Committee Chair, led a discussion of the evidence related to the safety, efficacy, and cost effectiveness of Electrical Neural Stimulation beginning with identification of key factors and health outcomes, and then a discussion of what evidence existed on those factors.

#### **1. Evidence availability and technology features**

- 1.1 The evidence based technology assessment report indicates that pain is burdensome and costly; an important and common medical concern and one of the most common causes of disability in the US. 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, headache, joint pain, aching and other musculoskeletal problems.
- 1.2 The evidence based technology assessment report indicates that electrical neural stimulation (ENS) is a commonly prescribed treatment. Different devices use electrical stimulation of nerves via pads on the skin, which are placed either at sites of pain or various other trigger locations, and delivering varying pulse, duration, and frequency of stimulation. Estimates of use are limited, but there were 275,000 reported ENS prescriptions in 1991. Proponents estimate 50% - 80% of chronic pain patients and 6% - 44% of acute pain patients benefit from ENS. However, although ENS has been widely adopted, it is unclear that benefit has been established for pain relief in high quality studies.
- 1.3 The evidence based technology assessment report searched peer reviewed medical literature, submitted comments and other sources and focused on summarizing and updating eight previously conducted Cochrane reviews that looked at a total of 86 studies. The Cochrane reviews included 3 to 25 randomized control trials each, and 6 new randomized control trials were identified. Overall many of the individual studies had limitations in size and design.
  - These articles addressed multiple ENS devices applied to different acute and chronic pain. The primary devices reported on were TENS - either 2 or 4 lead, with varying frequency and duration; ALTENS and PNT devices were also reported on. The different Cochrane reviews focused on various pain types such as acute, labor, chronic, low back, knee osteoarthritis, dysmenorrhea, and rheumatoid arthritis with the most numerous reports identified (25) for chronic pain.

- Three conditions (labor, knee osteoarthritis, and chronic pain) had a moderate overall strength of evidence for the studied outcomes related to efficacy (generally short term pain relief).
  - All others had either low or very low overall strength of evidence related to efficacy.
- 1.4 The evidence based technology assessment report identified 8 expert treatment guidelines, 6 included citations to evidence and included a Medicare national coverage decision that did not cite evidence. 5 guidelines indicated either insufficient evidence or did not recommend ENS; 3 guidelines indicated that the evidence supports or ENS is recommended for selected conditions. Medicare national coverage decision covers TENS for acute post-operative pain and TENS used longer than 30 days may be covered (by regional carriers) under durable medical equipment.
- 1.5 The committee also reviewed information provided by the state agencies, and public members; and heard comments from the evidence reviewer, HTA program, and agency medical directors.

## 2. Evidence about the technology's safety

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is safe. Summary of committee considerations follows.

- 1.6 The evidence based technology assessment report indicates that ENS is generally considered to be a safe therapy; other than minor skin irritation at the electrode site or discomfort with the stimulation, no major adverse events have been associated with its use. It is not recommended for patients with pacemakers, and electrodes should not be placed close to the carotid sinus, over the eyes, open wounds, irritated skin, or internally; and caution is recommended when using these devices on patients who are taking concomitant narcotic medications.

## 3. Evidence about the technology's efficacy and effectiveness

The committee discussed multiple key factors and health outcomes that were important for consideration in their overall decision on whether the technology is effective. Summary of committee considerations follows.

- 1.7 The evidence based technology assessment report indicates that ENS primary outcome measured were pain relief using many different measures, most commonly the 100mm visual analog scale (VAS) or the verbal numerical pain scale, with VAS being the preferred method for assessing pain intensity. Other outcomes for some studies included patient satisfaction, analgesic consumption, and functional improvement.
- 1.8 The evidence based technology assessment report identifies the pain relief threshold of at least 50% pain reduction as the conventional measure of clinically significant. Generally, pain changes were measured immediately after treatment which lasted generally lasted from immediately following or at acute events to several weeks or in a few studies, months. The reports do not consistently identify whether this threshold was used.
- 1.9 The report summarized the following eight Cochrane reviews and 6 additional RCTs published after the Cochrane reviews. Overall, the report concludes that evidence is insufficient for evidence based conclusions about efficacy or effectiveness of ENS due to mostly low or very low quality studies, though some indications and devices have somewhat higher quality evidence:
- *Acute Pain*: A total of 12 studies were included in one Cochrane review; that concluded most trials showed no statistically significant difference with ENS treatment for acute

- pain; and overall conclusion of low evidence base citing methodological issues of inadequate sequence generation, lack of blinding, unbalanced study groups; and incomplete follow up.
- *Labor Pain*: One Cochrane review comprised of 19 studies and one additional RCT located; concluding that evidence was limited and ENS does not seem to have any impact (positive or negative) on outcomes for mothers or babies.
  - *Dysmenorrhea*: A Cochrane review of 7 studies, some of which had small sample sizes, comparing low and high frequency TENS included; with mixed results, review authors did conclude high frequency TENS was more effective; but without sham and no treatment controls should be interpreted cautiously.
  - *Chronic pain*: A Cochrane review of TENS use for chronic pain (> 3 months) that included 25 studies (1281 participants). Overall evidence was moderate that patients treated with ENS were more likely to report overall positive effects of treatment compared to sham in first week of treatment but advantage decreased over time and most follow up did not exceed four weeks. Review authors concluded that literature lacks methodological rigor and reporting needed to make confident assessment of role of ENS in chronic pain and large multi-center RCTs of ENS are needed.
  - *Chronic Low Back Pain*: A Cochrane review of TENS included only four studies representing 585 persons. Two additional small RCTs were identified, most with small sample sizes. Of 6 total studies, only one study showed statistically significant pain relief compared to placebo. Review authors concluded that evidence from small placebo controlled trials does not support routine use of ENS in management of LBP.
  - *Osteoarthritis of the Knee*: A Cochrane review of seven studies (N=254) and two recently published RCTs were identified. Overall evidence considered moderate based on small sample sizes and mixed results of newer studies, ENS appears to be associated with clinically and statistically significant improvement in pain.
  - *Rheumatoid arthritis in the hand*: A Cochrane review of three small studies was identified. The studies were too heterogeneous with respect to TENS treatment (type, treatment schedule) to allow for meta-analysis and the studies concluded conflicting effects of ENS on outcomes in patients with RA.
  - *Neck Disorders*: A Cochrane review included 5 studies; with only one small study of the five reporting greater reduction in pain intensity for ENS group; review authors concluded definitive statements could not be made because current evidence on ENS is lacking, limited, or conflicting and future trials should include larger patient samples and precise standardization and description.
  - *Post-stroke Shoulder Pain*: A Cochrane review included 4 studies comparing ENS, functional electrical stimulation (FES) and high frequency TENS (HFTENS) with placebo or control. Only two of these studies assessed pain relief, so evidence for this outcome is overall very low and the 2 studies reported no significant effect.
  - *Cancer Pain*: A Cochrane review included two small studies of ENS effect on cancer pain and overall strength of evidence is rated very low given the extremely small evidence base which reported no significant difference.

1.10 The evidence based technology report overall, found few conclusions or reporting on functional outcomes, reduction in pain medication use, or patient satisfaction. Patient satisfaction was reported in labor pain (moderate quality higher satisfaction); no functional status outcomes were reported; and medication use was only reported on in dysmenorrhea (low quality, no difference).



#### 4. Evidence about the technology's value and cost-effectiveness

The committee discussed multiple key factors that were important for consideration in their overall decision on whether the technology has value and is cost-effective. Summary of committee considerations follows.

- 1.11 No economic studies on use of TENS for acute pain were identified; no full economic analysis were identified for chronic pain; though on simulated cost savings estimated savings from reduced medication and physical therapy visits ranging from \$240 to \$1052 over one year (1994).

#### Medicare Decision and Expert guidelines

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

- 1.12 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.
- 1.13 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 TENS 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).

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- (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 Conclusions**

Having made findings as to the most significant and relevant evidence regarding health outcomes, key factors and identified evidence related to those factors, primarily based on the evidence based technology assessment report, the committee concludes:

#### **1. Evidence availability and technology features**

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

- 1.1. 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.
- 1.2. 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.
- 1.3. 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.
- 1.4. 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 it safe?**

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

- 2.1. The committee agreed with the evidence report conclusions that indicated ENS is not associated with mortality.
- 2.2. 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.
- 2.3. 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.

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### 3. Is it 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).

- 3.1. 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.
- 3.2. 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).
- 3.3. No reliable information was available on important outcomes of reduction in analgesic medication, improvement in functional status, or quality of life.
- 3.4. 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.
- 3.5. 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.
- 3.6. The committee discussed the issue of comparators, ultimately deciding on treatment with ENS versus treatment without ENS.

### 4. Evidence about the technology's special populations, patient characteristics and adjunct treatment

The committee did not discuss other factors or special conditions related to efficacy as no high quality data supports efficacy or effectiveness.

### 5. Is it cost-effective?

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

- 5.1. 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.

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5.2. 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 (DME) costs.

**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 insignificant data to conclude it was effective in reducing pain relief, satisfaction and 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).

**Electrical Neural Stimulation Coverage Vote**

The clinical committee utilized their decision tool to first gauge committee judgment on the status of the evidence in the three primary areas of safety, efficacy, and cost.

Electrical Neural Stimulation Evidentiary Votes:

**Is there sufficient evidence under some or all situations that Electrical Neural Stimulation is:**

	<b>Unproven (no)</b>	<b>Equivalent (yes)</b>	<b>Less (yes)</b>	<b>More (yes)</b>
<b>Effective</b>	10	0	0	0
<b>Safe</b>	0	10	0	0
<b>Cost-effective Overall</b>	9	0	1	0

Electrical Neural Stimulation vote: Based on the evidence provided and the information and comments presented, the committee moved to a vote on coverage.

<b>HTCC COMMITTEE COVERAGE DETERMINATION</b>			
	<b>Not covered</b>	<b>Covered Unconditionally</b>	<b>Covered Under Certain Conditions</b>
<b>Electrical Neural Stimulation</b>	<b>8</b>	<b>0</b>	<b>2</b>



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Outcome: The committee chair directed HTA staff to prepare a Findings and Decision document on Electrical Neural Stimulation reflective of the majority vote for final approval at the next public meeting.

- Electrical Neural Stimulation is not covered. This decision applies to use of durable medical equipment ENS device and supplies outside of medically supervised facility settings (e.g. in home use).