

Agency Medical Director Comments

Electrical Nerve Stimulation



**Washington State
Health Care Authority**



Electrical Nerve Stimulation

Approved for marketing* by the FDA
for:

- Tx of pain
- Tx of pain caused by osteoarthritis

*Approval process -510(k)- does not
require demonstration of efficacy.



Transcutaneous Electrical Nerve Stimulation (TENS)

- Originally introduced for Rx of neural pain on basis of Melzack/Wall theory of spinal pain modulation
- Use of technology has spread primarily to non-neural pain (eg, 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 in function?
- Value: Costs are cumulative and related to ongoing rental/purchase of equipment and disposable accessories (eg, leads, skin patches, custom garments with built in electrodes, etc)



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.”



Updated Cochrane Review

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

State Agency Utilization Data

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
Total	5,340	6,691	7,532	9,011	28,574

* 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
Total	1,795	2,170	2,687	3,016

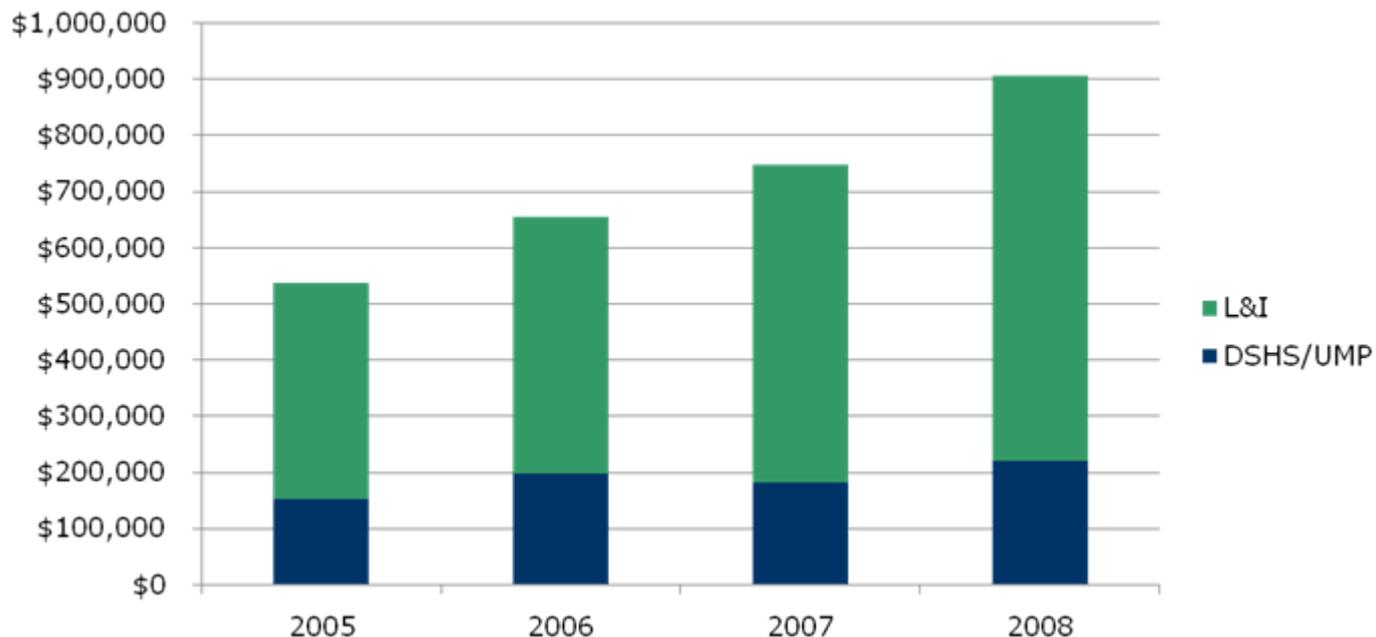


Total* Payments for Electrical Nerve Stimulators

Device Payments by Year

UMP, Medicaid & L&I

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





Utilization Summary

- Per patient costs relatively stable.
- Recent trend upward in total expenditures.
- Some claim experience shows extended rental periods (many months).
- Increase appears due to more injured workers receiving TENS treatment.



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



SPECTRUM RESEARCH, INC.



A Health Technology Assessment

Transcutaneous Electrical Nerve Stimulation for the Treatment of Pain

Health Technology Clinical Committee Meeting
Washington State Health Technology Assessment Program

October 30, 2009

Seattle, WA

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Scope of Report



This report critically summarizes relevant Cochrane reviews and recently published research examining the use of transcutaneous electrical nerve stimulation for the treatment of pain

The report focuses on the highest quality evidence available based on systematic review of the literature

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

Background

- Transcutaneous electrical nerve 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

Key Questions

- Key Question 1:** What is the evidence of efficacy and effectiveness of TENS for the treatment of acute and chronic pain?
- Key Question 2:** What is the evidence about the safety profile for TENS?
- Key Question 3:** What is the evidence of cost implications and cost effectiveness of TENS?

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
- TENS and other non-invasive forms of ENS
 - ▣ Interferential (IFC) therapy (also called diadynamic)
 - ▣ Percutaneous neuromodulation therapy (PNT)
- *Did not include* percutaneous electrical nerve stimulation (PENS), acupuncture/electroacupuncture, spinal cord stimulation, deep brain stimulation

Inclusion Criteria: New RCTs

- Randomized controlled trials (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
- Inclusion and exclusion criteria for individual RCTs published after the currently available Cochrane Review correspond to those described in the individual review (i.e. whatever criteria the review used, we did as well)

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
- 1,676 potentially relevant recent randomized controlled trials

Primary Data Source: Overview

Key Questions 1 and 2

- 10 Cochrane Reviews (1998-2009)
 - One review on use of TENS for the treatment of headache was excluded because TENS given as part of a multimodal treatment
 - Included: acute pain, labor pain, primary dysmenorrhea, chronic pain, osteoarthritis of the knee, chronic low back pain, rheumatoid arthritis in the hand, post-stroke shoulder pain, neck disorders, and cancer pain

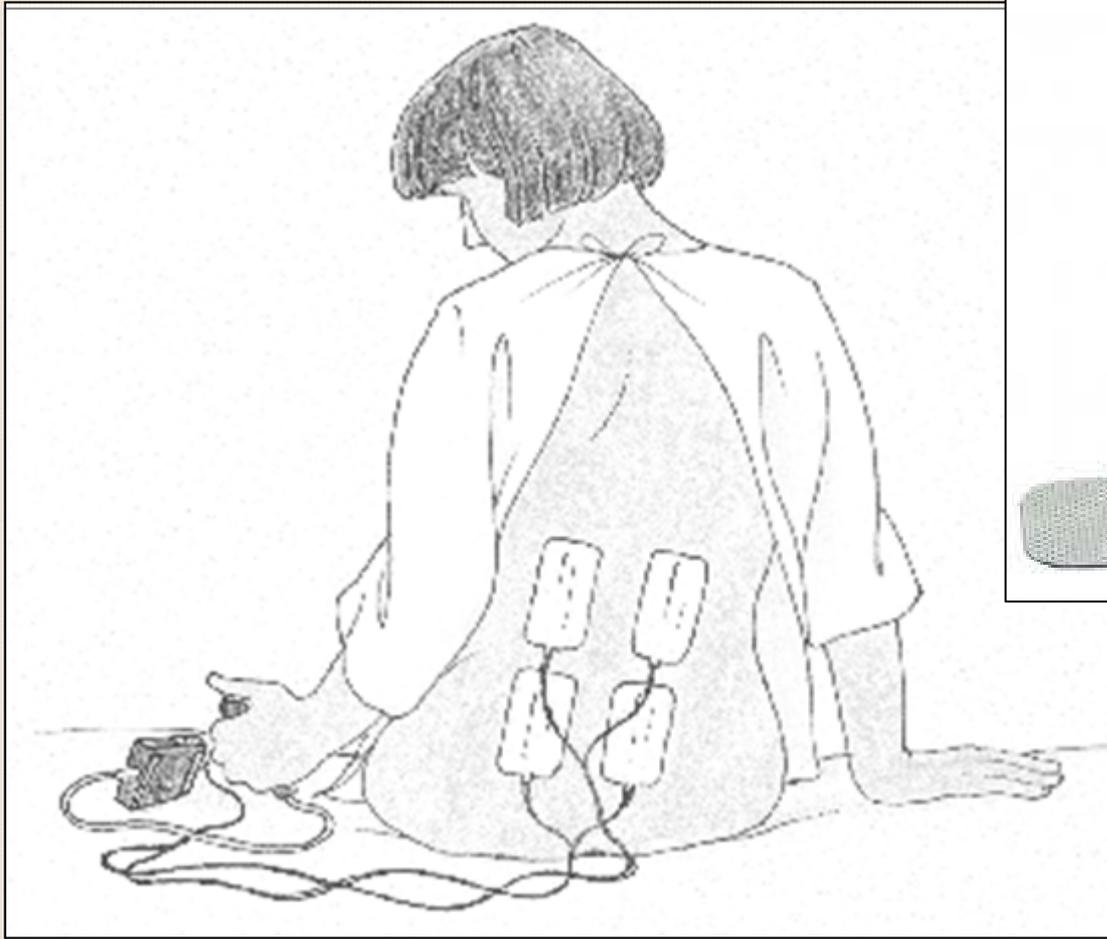
Primary Data Source: Overview

- 6 recent randomized controlled trials
 - TENS for the treatment of osteoarthritis of the knee, chronic low back pain, labor pain, and dysmenorrhea
 - Percutaneous neuromodulation therapy for the treatment of osteoarthritis of the knee

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

Interventions



Interventions

- **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

Interventions

- **Pulse duration (width)** set anywhere from 10-1000 μsec
 - Generally shorter for conventional TENS (e.g. 40-75 μsec) than for acupuncture-like TENS (ALTENS; e.g. 150-250 μsec)
- **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 stimulation, deep brain stimulation)

Outcome Measures

Primary outcome: Difference between pre- and post-treatment pain intensity, measured with a visual analog scale (VAS) or other validated measure

Key Questions 2 and 3: Adverse effects, economic parameters

Secondary outcomes: patient satisfaction, analgesic consumption, functional status

Definitions: 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 'worst pain possible'; alternatively, they can be labeled 'no pain relief' and 'complete relief of pain'

Verbal numerical scale: Correlates well with 100mm VAS scores; 0 corresponds to 'no pain' and 10 to 'maximum pain possible'; alternatively, they can correspond to 'no relief' and 'complete relief'

Definition: Standardized Mean Difference

Standardized mean difference (SMD): Difference in means (e.g. mean improvement in VAS) between treatment groups, divided by the pooled standard deviation of the measurements

- Dimensionless – so different scales become uniform
- Useful for comparing studies that measure the same outcomes, but use different methods to do it

That's great, but what does it mean?

Interpretation of SMD

Statistical Significance

- Consider the magnitude of the SMD estimate along with its associated 95% confidence interval
- If the interval crosses the null value of 0, then the estimate is not statistically significant

Clinical Importance

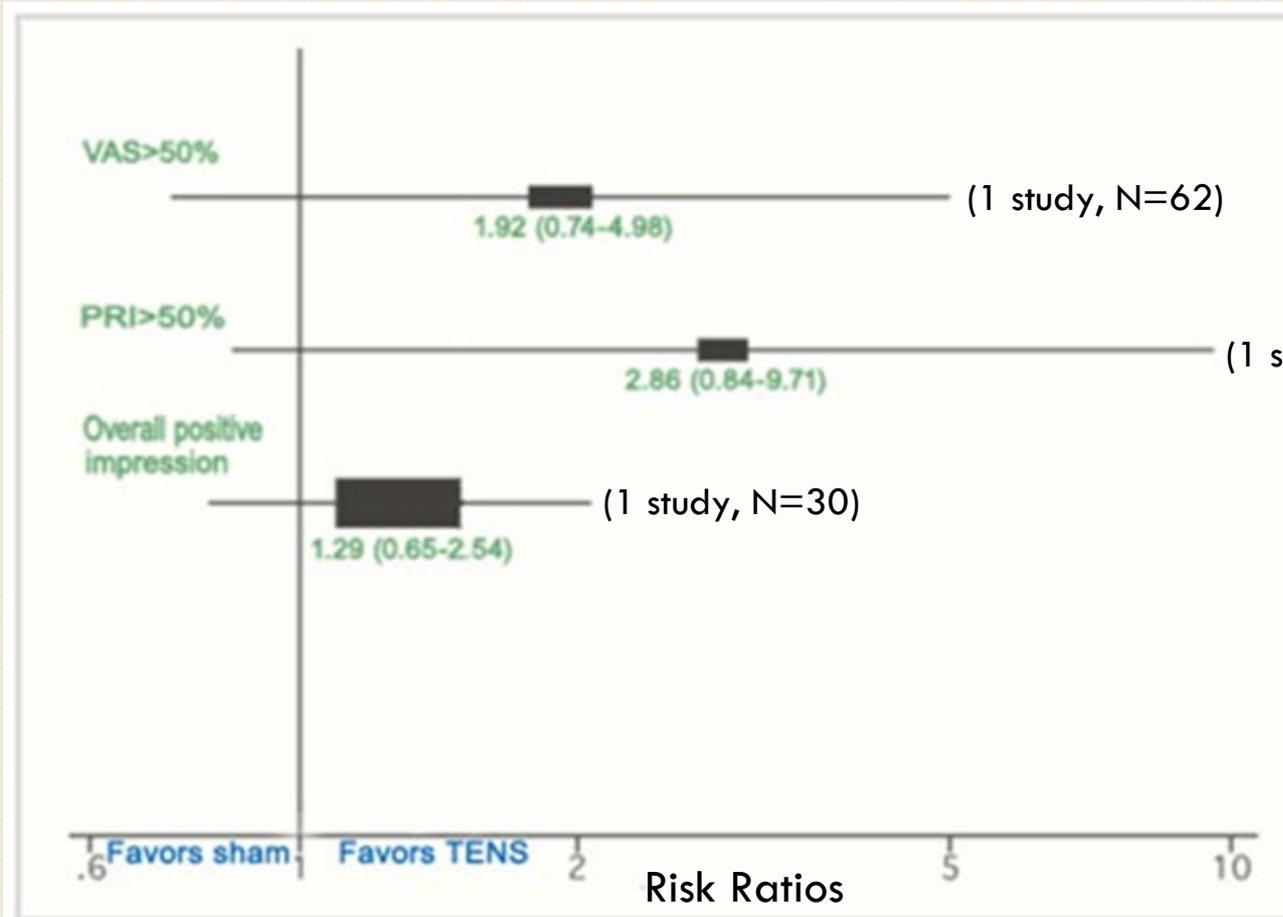
- Defined in many ways, depending on conditions and opinions of individual investigators or panels
- One widely used **rule of thumb** for using SMD:
 - 0.2 = small effect
 - 0.5 = moderate effect
 - 0.8 = large effect

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), hemophilic pain, acute trauma (e.g. sprains or fractures), postpartum contraction, acute oro-fascial pain, post thoracotomy, rib fractures, and neuropathic pain

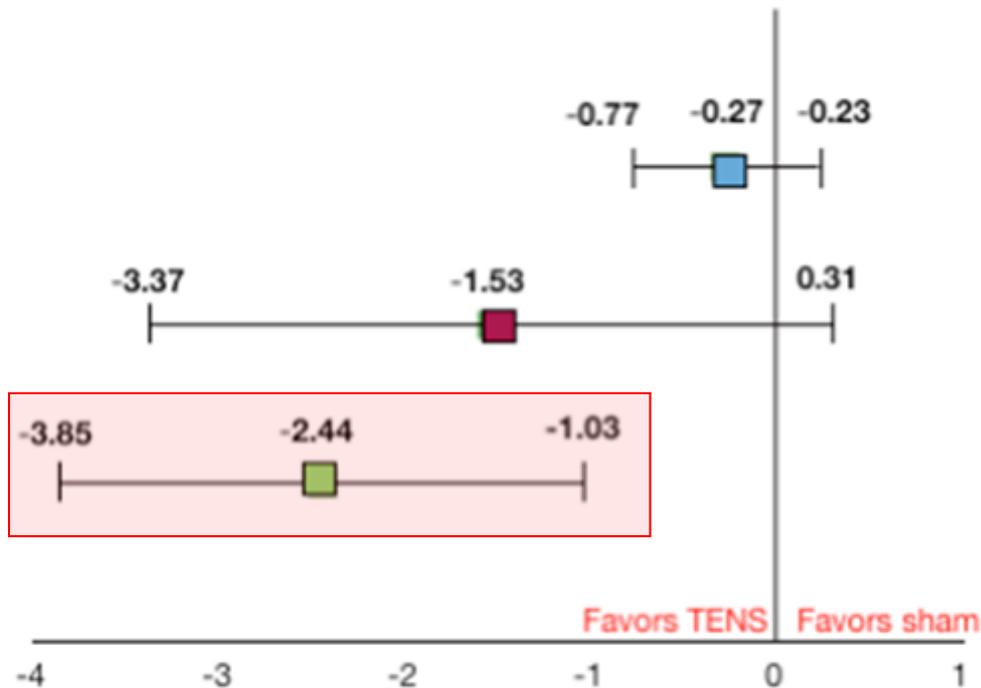
Key Question 1: Summary of Findings for Efficacy and Effectiveness for Acute Pain

- Pain reduction of at least 50%, measured by VAS or pain rating index
- Overall impression with TENS defined as rating excellent/good on 4-category scale



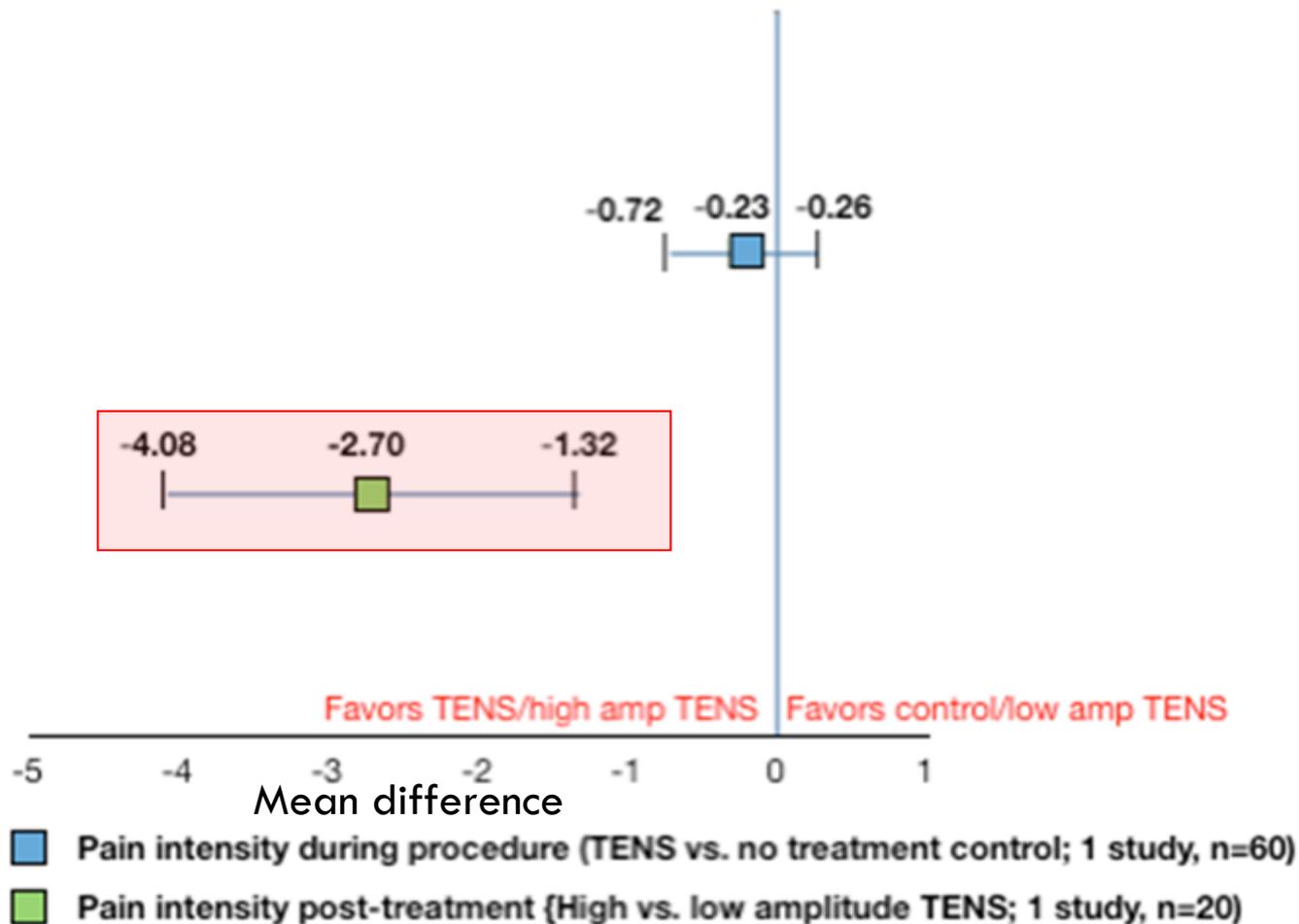
Key Question 1: Summary of Findings for Efficacy and Effectiveness for Acute Pain

Mean difference in pain intensity between TENS and sham treatment



- Pain intensity during procedure, numerical rating scale (1 study, n=60)
- Pain intensity post-treatment, visual analogue scale (1 study, n=30)
- Pain intensity after 2 days treatment, visual analogue scale (1 study, n=50)

Key Question 1: Summary of Findings for Efficacy and Effectiveness for Acute Pain



Key Question 1: Summary of Findings for Efficacy and Effectiveness for Acute 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 SoE: LOW

Key Question 1: Summary of Findings for Efficacy and Effectiveness for Labor Pain

	No. studies	N	RR (95% CI)	SMD (95% CI)	Favors TENS
Back					
Severe pain in labor *	2	147	0.77 (0.60, 1.00)		-
Mean pain score in labor *	2	299		-0.16 (-0.39, 0.07)	-
Other analgesics needed *	5		0.88 (0.76, 1.01)		-
Analgesic consumption	2	358		-0.09 (-0.33, 0.14)	-
Epidural required	5	571	0.99 (0.59, 1.67)		-
Satisfied with pain relief *	5	452	1.25 (0.98, 1.60)		-
Would use TENS again	4	583	1.54 (1.31, 1.80)		+
Acu-points					
Severe pain in labor *	2	190	0.41 (0.32, 0.55)		+
Epidural required	1	100	0.40 (0.08, 1.97)		-
Satisfied with pain relief *	1	90	4.81 (1.81, 9.29)		+
Would use TENS in future	1	100	1.45 (1.18, 1.79)		+

+ = favors TENS
-- = favors sham

Key Question 1: Summary of Findings for Efficacy and Effectiveness for 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 SoE: MODERATE

Key Question 1: Summary of Findings for Efficacy and Effectiveness for 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

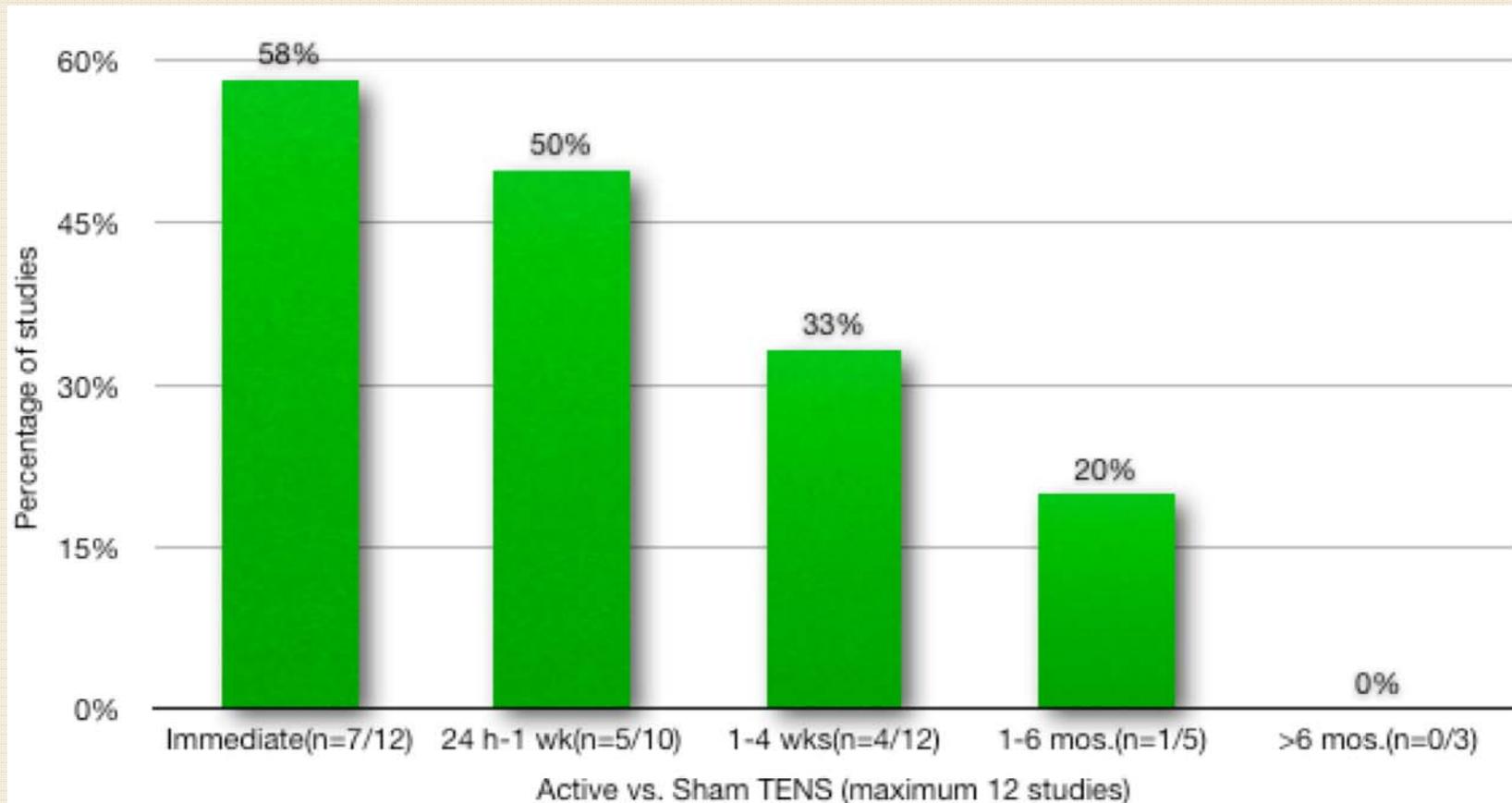
Overall SoE: LOW

Key Question 1: Summary of Findings for Efficacy and Effectiveness for Chronic Pain

- Included 25 studies (N=1 281); did not present individual-study level data
- Pain associated with rheumatoid arthritis, osteoarthritis, pancreatitis, myofascial pain, diabetic neuropathy, and low back pain

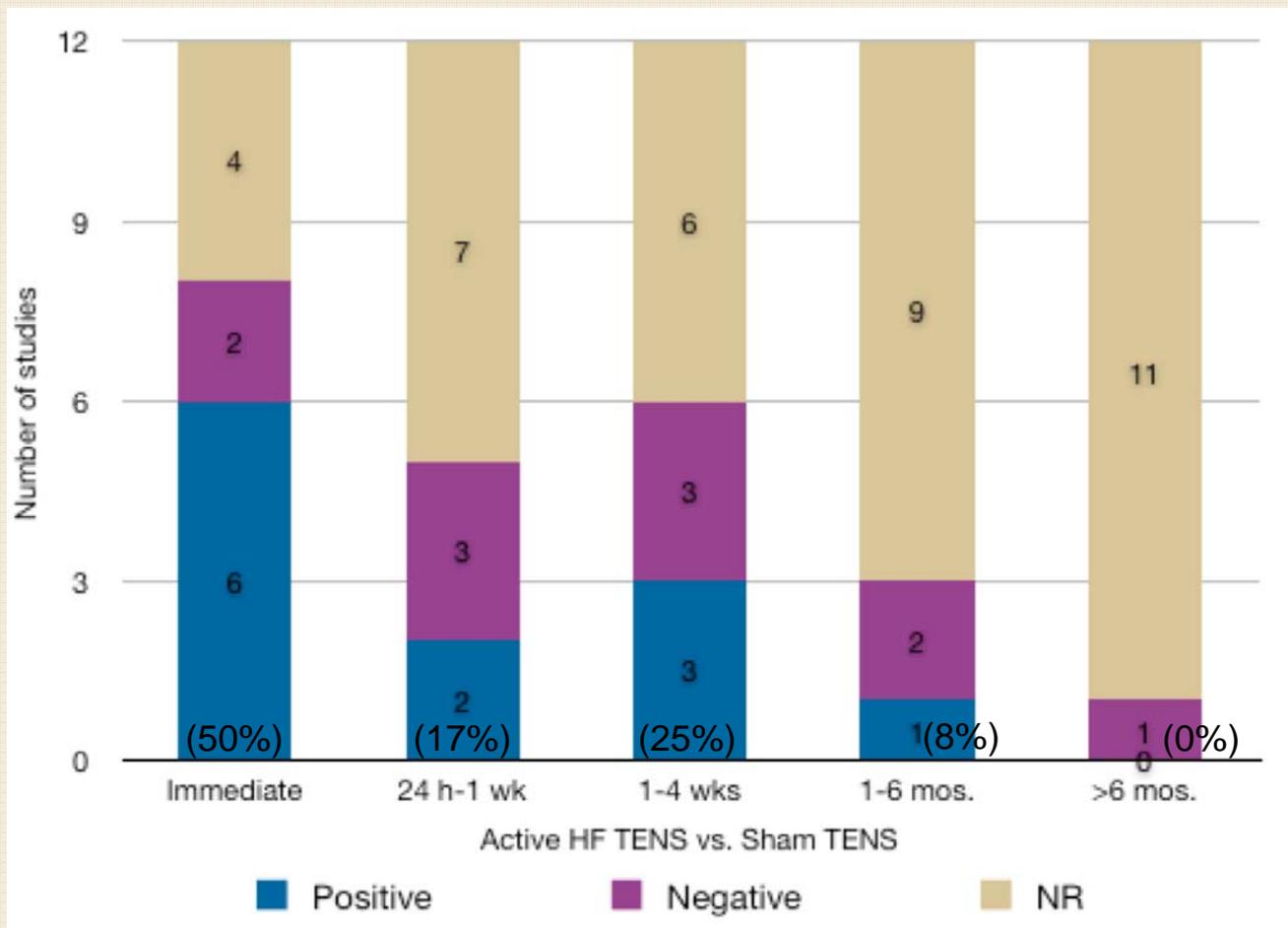
Key Question 1: Summary of Findings for Efficacy and Effectiveness for Chronic Pain

Proportion of studies of TENS vs. sham for which an overall positive effect of TENS for treatment of chronic pain (at different times post-treatment) was described



Key Question 1: Summary of Findings for Efficacy and Effectiveness for Chronic Pain

Evidence for analgesic efficacy after active HFTENS compared with sham for the treatment of chronic pain over time

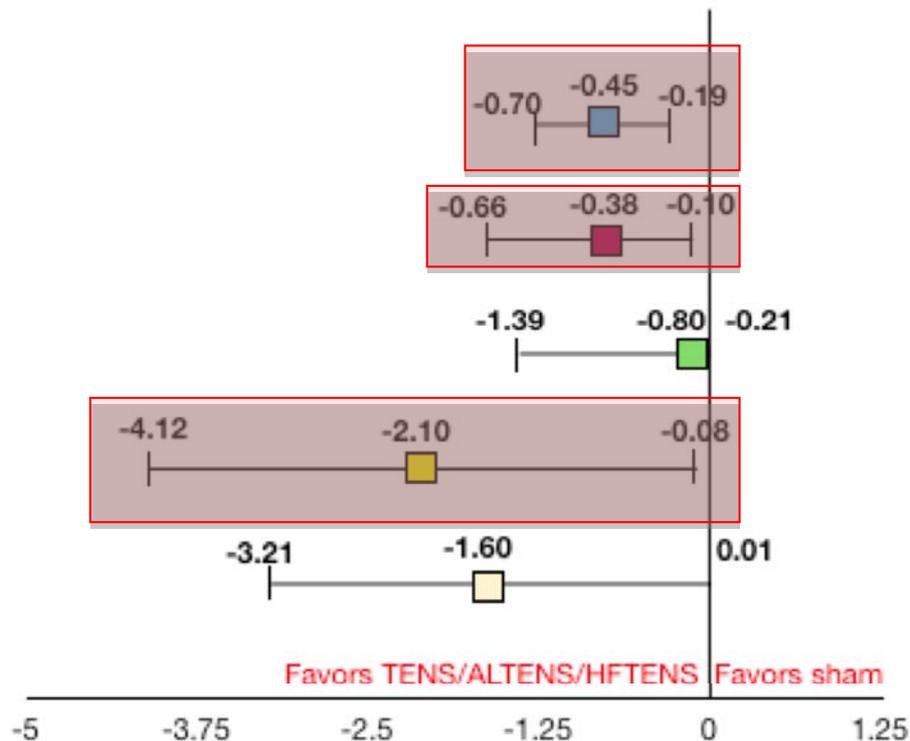


Key Question 1: Summary of Findings for Efficacy and Effectiveness for Chronic Pain

- 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 SoE: MODERATE

Key Question 1: Summary of Findings for Efficacy and Effectiveness for Osteoarthritis of the Knee

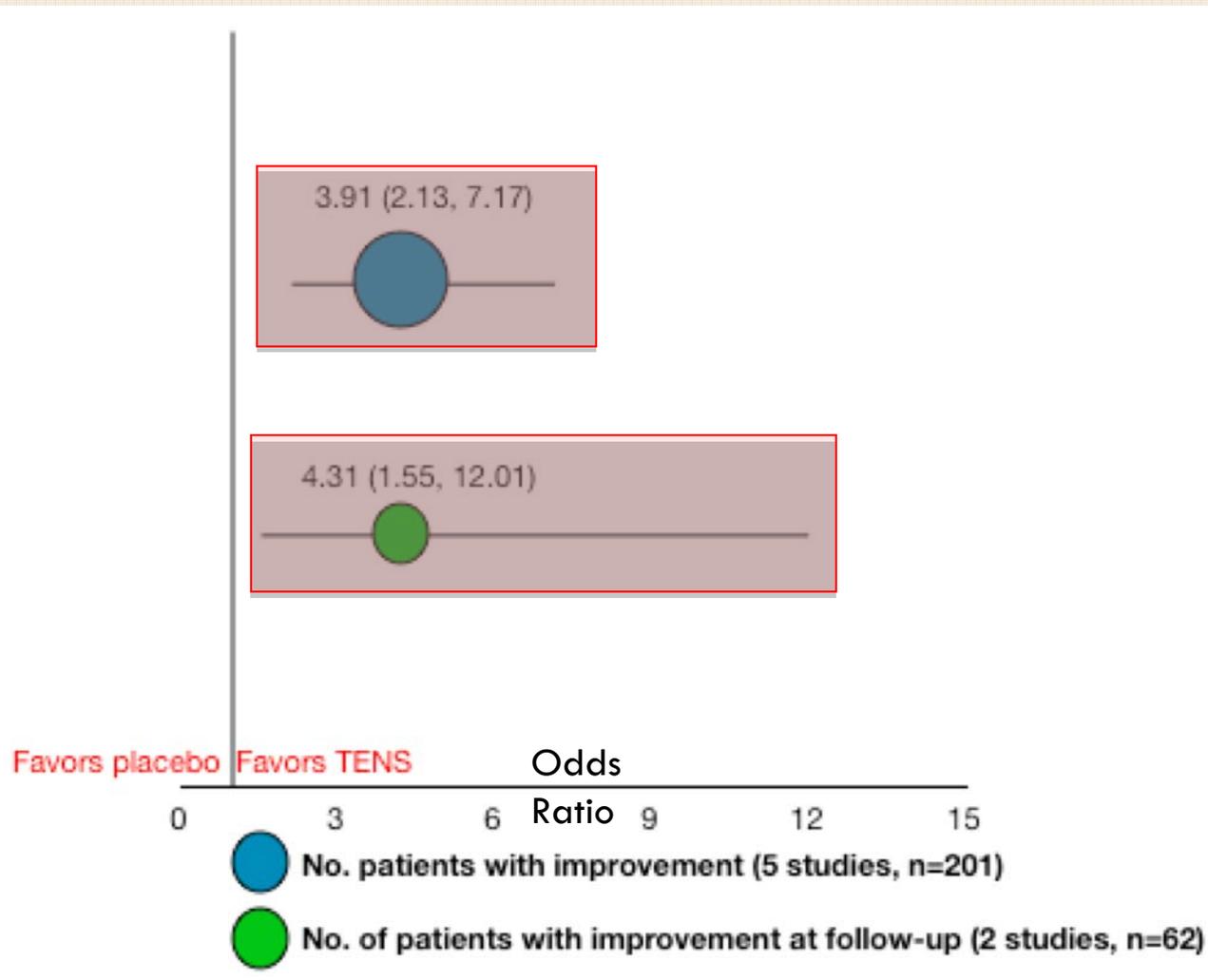


- TENS and/or ALTENS vs. placebo (6 studies, n=254)
- TENS vs. placebo (5 studies, n=214)
- ALTENS vs. placebo (1 study, n=50)
- HFTENS vs. placebo (1 study, n=40)
- Burst mode TENS vs. placebo (1 study, n=40)

Mean differences in VAS pain relief experienced between TENS/ALTENS, TENS alone, HFTENS, high burst TENS, and placebo (sham)

Included total of 7 studies (N=294)

Key Question 1: Summary of Findings for Efficacy and Effectiveness for Osteoarthritis of the Knee



Comparison of pain improvement between TENS and placebo groups immediately following treatment and during follow-up

Key Question 1: Summary of Findings for Efficacy and Effectiveness for Osteoarthritis of the Knee

Table 18. Comparisons between TENS and placebo TENS, indicating for which analyses TENS was favored for treatment of osteoarthritis of the knee (pain relief measured by VAS and patient-reported improvement).⁸

Pain improvement	Subgroup analyses					
	Main analysis	Single study analysis	High quality studies	Low quality studies	Single TENS application or duration <4 wks	Repeated TENS applications or duration 4+ wks
TENS/ALTENS vs. placebo	+		+	-	-	+
TENS/HFTENS vs. placebo	+	+				
ALTENS vs. placebo	+					
Burst mode TENS vs. placebo		-				

* + = TENS favored; - = TENS not favored.

Key Question 1: Summary of Findings for Efficacy and Effectiveness for Osteoarthritis of the Knee

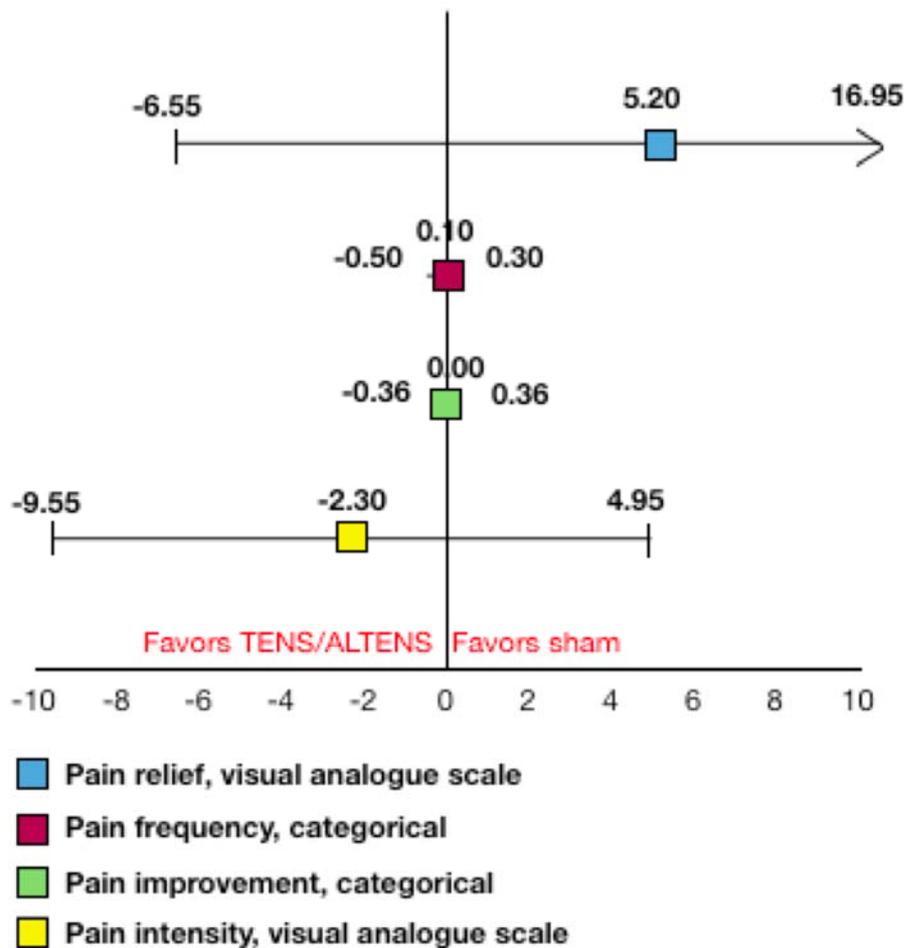
- Statistically significant reductions in knee pain with TENS treatment compared to sham (6 studies, N=254)
- Patients treated with TENS were four times as likely to report improvements in knee pain immediately after treatment (5 studies, N=214) and during follow-up (2 studies, N=62) when compared to sham
- In subgroup analyses, knee pain improvement was statistically significant in high quality studies, studies of repeated TENS applications, and studies with treatment durations of at least 4 weeks
- In one recent RCT, percutaneous neuromodulation therapy was better at reducing knee pain than sham immediately post-treatment, but there were no significant differences at 6, 24 or 48 hours of follow-up

Key Question 1: Summary of Findings for Efficacy and Effectiveness for Osteoarthritis of the Knee

- 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
- Using the criterion of 0.80 to indicate a large effect, differences in pain relief when comparing TENS/ALTENS to placebo could be considered clinically important

Overall SoE: MODERATE

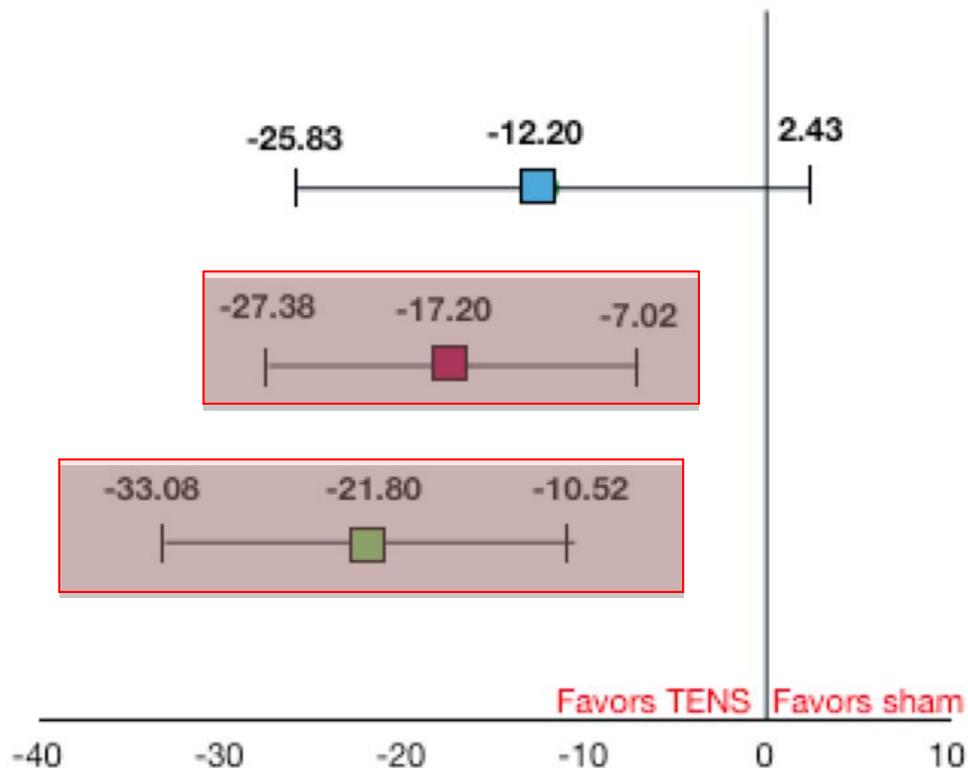
Key Question 1: Summary of Findings for Efficacy and Effectiveness for Chronic Low Back Pain



Mean differences in pain relief and pain intensity measured by VAS and pain improvement and pain frequency in comparisons of conventional TENS +/- ALTENS vs. placebo at the end of four weeks treatment (1 study, N=125)

Included 4 studies (N=585)

Key Question 1: Summary of Findings for Efficacy and Effectiveness for Chronic Low Back Pain



Mean differences in pain intensity and activity pain (measured by VAS) at the end of two weeks treatment in two studies comparing TENS to placebo

- Pain intensity, visual analogue scale (1 study, n=22)
- Reduced activity pain, visual analogue scale (1 study, n=27)
- Reduced pain intensity, visual analogue scale (1 study, n=27)

Key Question 1: Summary of Findings for Efficacy and Effectiveness for 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
- 3 studies including functional outcomes only observed differences for ALTENS/Oswestry (N=27) and ALTENS isolift (N=167)
- 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 SoE: LOW

Key Question 1: Summary of Findings for Efficacy and Effectiveness for 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 SoE: VERY LOW

Key Question 1: Summary of Findings for Efficacy and Effectiveness for 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 SoE: LOW

Key Question 1: Summary of Findings for Efficacy and Effectiveness for 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 SoE: VERY LOW

Key Question 1: Summary of Findings for Efficacy and Effectiveness for 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 SoE: 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 SoE: 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
- 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
- This information only represents cost information, however, and does not inform on cost-effectiveness

Overall SoE: VERY LOW

What We Know

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

What We Know

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

What We Know

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

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
- Preponderance of use for chronic pain prescribed for months

Remaining Questions

- 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

HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on these questions:

1. Is it safe?
2. Is it effective?
3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

Principle One: Determinations are Evidence based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective¹ as expressed by the following standards.²

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms.³

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.
- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

¹ Based on Legislative mandate: See RCW 70.14.100(2).

² The principles and standards are based on USPSTF Principles at: <http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm>

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Using Evidence as the basis for a Coverage Decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

1. *Availability of Evidence:*

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

2. *Sufficiency of the Evidence:*

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence⁴ using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- the amount of evidence (sparse to many number of evidence or events or individuals studied);
- consistency of evidence (results vary or largely similar);
- recency (timeliness of information);
- directness of evidence (link between technology and outcome);
- relevance of evidence (applicability to agency program and clients);
- bias (likelihood of conflict of interest or lack of safeguards).

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

3. *Factors for Consideration - Importance*

At the end of discussion at vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- risk of event occurring;
- the degree of harm associated with risk;
- the number of risks; the burden of the condition;
- burden untreated or treated with alternatives;
- the importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- the degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- value variation based on patient preference.

⁴ Based on GRADE recommendation: <http://www.gradeworkinggroup.org/FAQ/index.htm>

Medicare Coverage and Guidelines

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
CMS Coverage Database, #35 - 46	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. <ul style="list-style-type: none"> ○ 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. 	NR	
Guidelines – WA HTA p. 25 <i>University of Iowa Gerontological Nursing Interventions Research Center, Research Translation and Dissemination Core</i>		There is good evidence that transcutaneous electrical nerve stimulation (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 or inconclusive. Referral to trained specialists is recommended for all physical modalities of treatment. This guideline did not refer to other types of persistent pain or the use of percutaneous neuromodulation therapy (PNT). <ul style="list-style-type: none"> ○ TENS reduced pain in knee osteoarthritis and in chronic back pain 	Yes	Grade = B
Guidelines – WA HTA p. 25 <i>American College of Occupational and Environmental Medicine (ACOEM)</i>		Occupational medicine practice guidelines: evaluation and management of common health problems and functional recovery in workers. The only recommendation for use of TENS therapy by the ACOEM 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 electrical nerve stimulation modalities were not recommended or described. <ul style="list-style-type: none"> • TENS (single or dual channel) is recommended for select use in chronic low back pain or chronic radicular pain syndrome as an adjunct for more efficacious treatments (<i>Evidence Grade = C</i>) • TENS is not recommended for acute or subacute LBP or acute radicular pain syndromes (<i>Evidence Grade = I, insufficient evidence</i>) 	Yes	Grade = C Grade = I, Insufficient
Guidelines – WA HTA p. 25		The Ottawa Panel's evidence-based practice guidelines on electrotherapy for the		

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
<i>Ottawa Panel evidence-based clinical practice guidelines for electrotherapy and thermotherapy interventions in the management of rheumatoid arthritis in adults.</i>		<p>management of rheumatoid arthritis are generally in accordance with other evidence-based practice guidelines, including those from the American College of Rheumatology, the American Pain Society, and the American Occupational Therapy Association. Overall, only low frequency TENS applied to the hand and wrist showed a small clinical benefit. The following is a summary of their findings.</p> <ul style="list-style-type: none"> • Low-frequency TENS applied to the hand and wrist versus no stimulation (<i>Evidence Grade = I (RCT): Grade A for pain at 3 weeks (clinically important benefit), grade C+ for 10 of 14 power at 3 weeks (clinical benefit), grade C for work at 3 weeks, no benefit).</i> • High-frequency TENS applied to the hand and wrist versus placebo, <i>Evidence Grade = I (RCT): Grade C for pain and joint tenderness, same day, no benefit).</i> • High- versus low-frequency TENS applied to the hand and wrist, (<i>Evidence Grade = I (RCT): Grade C for global patient (patient's assessment of overall disease activity or improvement)³² at 2 weeks, clinical benefit).</i> (<i>Evidence Grade = I, insufficient evidence)</i> 	Yes	<p>Grade= I, A, C+, C</p> <p>Grade I, C</p> <p>Grade I, C</p>
<p>Guidelines – WA HTA p. 25</p> <p><i>Institute for Clinical Systems Improvement (ICSI)</i></p>		In a guideline describing several treatments for headache, the ICSI found TENS units for migraine or muscle contraction headache have not been found to be more beneficial than placebo when evaluated in a controlled study.	Yes	
<p>Guidelines – WA HTA p. 25</p> <p><i>National Headache Foundation</i></p>		According to the National Headache Foundation, the use of TENS has been reserved primarily for the treatment of body or extremity pains because of fear of potential epileptogenic effects of electric current running through the head. With proper placement of electrodes and the use of low-intensity currents, it appears to be safe to apply this technique to the head. However, there is little objective evidence about the efficacy of TENS. Considering the inconvenience and the limited efficacy, this treatment was not recommended.		
<p>Guidelines – WA HTA p. 25</p> <p><i>European Federation of Neurological Societies (EFNS)</i></p>		The EFNS stated it was difficult to come to conclusive recommendations for the use of TENS. There were a limited number of patients with ascertained neuropathic pain, diseases, comparators, and the results varied considerably from study to study. Stimulation parameters also vary considerably between	Yes	Grade = C

Organization	Date	Outcome	Evidence Cited?	Grade / Rating
<i>guidelines on neurostimulation therapy for neuropathic pain</i>		the studies, using different pulse waveforms and a wide range of frequencies, in addition to the number and duration of the sessions. They concluded standard high-frequency TENS might be better than placebo.		
Guidelines – WA HTA p. 25 <i>[Stroke Rehabilitation] Clinical practice guidelines for transcutaneous electrical nerve stimulation (TENS)</i>		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).	NR	
Guidelines – WA HTA p. 25 <i>American Pain Society</i>		In a published guideline from the American Pain Society (APS), it was concluded that 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 (as part of an interdisciplinary rehabilitation approach) for patients with low back pain.	Yes	Insufficient

HEALTH TECHNOLOGY EVIDENCE IDENTIFICATION

Discussion Document: What are the key factors and health outcomes and what evidence is there?

	High Frequency TENS	Low Frequency TENS
Safety		
Mortality		
Morbidity		
Efficacy - Effectiveness		
Pain Reduction		
Improves Function		
Patient Satisfaction		
Analgesic Consumption		
Other		
Special Population / Considerations		
Acute Pain		
Labor Pain		
Primary Dysmenorrhea		
Chronic Pain		
OA of the Knee		
Chronic Low Back Pain		
RA in the hand		
Neck Disorder		
Post-Stroke Shoulder Pain		
Cancer Pain		
Other		
Cost		

Safety Outcomes	Safety Evidence
Mortality - Overall Mortality	
Morbidity -	
Efficacy/Effectiveness Outcomes	Efficacy/Effectiveness Evidence
Cost Outcomes	Cost Evidence
Other Factors	Evidence
Special Populations	

Clinical Committee Evidence Votes

First voting question

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

Is there sufficient evidence under some or all situations that the technology is:

	Unproven (no)	Equivalent (yes)	Less (yes)	More (yes)
Effective				
Safe				
Cost-effective				

Discussion

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

Second vote

Based on the evidence about the technologies' safety, efficacy, and cost-effectiveness, it is

_____ Not Covered. _____ Covered Unconditionally. _____ Covered Under Certain Conditions.

Discussion Item

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

Clinical Committee Findings and Decisions

Next Step: Cover or No Cover

If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

Next Step: Cover with Conditions

If covered with conditions, the Committee will continue discussion.

- 1) Does the committee have enough information to identify conditions or criteria?
 - Refer to evidence identification document and discussion.
 - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
 - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

- 2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
 - What are the known conditions/criteria and evidence state
 - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff ; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

Efficacy Considerations:

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
 - Direct outcome or surrogate measure
 - Short term or long term effect
 - Magnitude of effect
 - Impact on pain, functional restoration, quality of life
 - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?
- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy
 - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices

Safety

- What is the evidence of the effect of using the technology on significant morbidity?
 - Frequent adverse effect on health, but unlikely to result in lasting harm or be life-threatening, or;
 - Adverse effect on health that can result in lasting harm or can be life-threatening.
- Other morbidity concerns
- Short term or direct complication versus long term complications
- What is the evidence of using the technology on mortality – does it result in fewer adverse non-fatal outcomes?

Cost Impact

- Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

Overall

- What is the evidence about alternatives and comparisons to the alternatives
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?