

Health Technology Clinical Committee

Findings and Coverage Decision

Topic: Spinal Cord Stimulation

Meeting Date: August 20th, 2010

Final Adoption: October 22nd, 2010

Number and Coverage Topic

20100820B – Spinal Cord Stimulation

HTCC Coverage Determination

Spinal Cord Stimulation for chronic neuropathic pain is **not a covered benefit**.

HTCC Reimbursement Determination

- **Limitations of Coverage**
 - N/A
- **Non-Covered Indicators**
 - N/A
- **Agency Contact Information**

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

Health Technology Background

The Spinal Cord Stimulation topic was selected and published in December 2009 to undergo an evidence review process. Spinal Cord Stimulation (SCS) is an alternative treatment proposed for patients with chronic neuropathic pain who have not responded to conventional therapies such as medication, physical and/or psychological therapy, and in some case, reoperation. Current best evidence is available primarily from four trials on 375 patients; which are rated at a Level 1 or 2 (good quality), which is a better level of evidence than some interventions. However, total patient sample size is small, comparators were weak or inappropriate, reported outcomes are mostly subjective and not consistently reported, industry funding and management may have an impact, and no trial included a sham stimulation/procedure arm. The overall body of evidence was inconsistent, with several trials showing benefits on some outcomes at generally shorter follow up periods and others showing no difference. SCS is an implanted, long term treatment, but no evidence exists on either long term efficacy or safety.

The committee agreed that SCS is less safe than alternatives, is an invasive procedure, and has many adverse events. While conventional medical management is not invasive, so would generally have a lower risk profile, reoperation is also a comparator and had less complications. SCS device related complications can be serious and include dural punctures, amplitude by bodily movements; paresthesia in other body parts, pain, disturbed urination, lead fracture, loss of effect, infection. Indications for SCS (FDA): Chronic intractable pain in the trunk and/or limbs including unilateral or bilateral pain associated with FBSS and intractable low back and leg pain, and for some devices: *CRPS, radicular pain syndrome or radiculopathies resulting in pain, post-laminectomy pain, unsuccessful disc surgery, degenerative disc disease or herniated disc pain refractory to conservative or surgical interventions, peripheral causalgia, epidural fibrosis, arachnoiditis or lumbar adhesive arachnoiditis, and multiple back surgeries*. Potential patients should undergo a period of trial stimulation prior to permanent SCS implantation. Contraindications for SCS (FDA): Failed trial stimulation due to ineffective pain relief; poor surgical risks; pregnancy; active general infections or multiple illnesses; inability to operate the SCS system; and cardiac pacemakers (with specific exceptions and precautions) or cardioverter defibrillators.

In June 2010, the HTA posted a draft and then followed with a final report from a contracted research organization that reviewed publicly submitted information; searched, summarized, and evaluated trials, articles, and other evidence about the topic. The comprehensive, public and peer reviewed Spinal Cord Stimulation report is 164 pages, and identified a relatively large amount of literature.

An independent group of eleven clinicians who practice medicine locally meet in public to decide whether state agencies should pay for the health technology based on whether the evidence report and other presented information shows it is safe, effective and has value. The committee met on August 20, reviewed the report, including peer and public feedback, and heard public and agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at <http://www.hta.hca.wa.gov> under the committee section.

Committee Findings

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

1. Evidence availability and technology features

The committee concludes that the best available evidence on Spinal Cord Stimulation has been collected and summarized. The evidence is presented below:

- *Condition:* The evidence based technology assessment report indicates that neuropathic pain is pain resulting from a primary lesion or dysfunction in the central or peripheral nervous system. Chronic neuropathic pain is likely underdiagnosed and undertreated; its estimated prevalence has been reported to range from 1.5 to 8%. Stimulation before having the device permanently implanted. The evidence based technology assessment report indicates the aim of treatment for chronic pain is to improve function and quality of life while relieving pain. Treating chronic neuropathic pain is challenging, as the pain is often refractory to conservative therapies.
 - The two of the most common types of chronic neurogenic pain treated with spinal cord stimulation include failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS).
 - FBSS has been estimated to affect approximately 30% of patients following lumbar spine surgery, though reported estimates range from 10 to 40%.
 - Complex regional pain syndrome (CRPS) is a neuropathic pain disorder of unknown pathophysiology that affects one or more limbs.
- *Technology and alternatives:* The evidence based technology assessment report indicates spinal cord stimulation (SCS) is an alternative treatment proposed for patients with chronic neuropathic pain who have not responded to conventional therapies such as medication, physical and/or psychological therapy, and in some cases, reoperation.
 - Potential benefits include pain relief, improved quality of life and functionality, reduction in pain medication usage. Implantation of SCS components is minimally invasive (compared to back surgery) and is reversible. Patients typically undergo a trial period.
- *Outcomes:* Patient oriented outcomes of interest include measures of pain relief, improved function, reduction of medication, quality of life, and patient satisfaction. The evidence based technology assessment report indicates many pain related outcomes are subjective, and considerable debate remains about clinically meaningful differences.
 - Reduction in pain is the most commonly reported outcome, and a greater than 50% reduction on a VAS pain intensity is commonly used to determine success, though more studies are needed to determine significance.
- *Evidence Base:* The evidence based technology assessment report focuses on three RCTs and one prospective cohort study, and includes additional case series and cost studies, as well as guidelines.
 - One RCT included patients with CRPS; two RCTs included patients with FBSS. The prospective cohort study included patients with chronic pain and an open Washington state workers' compensation claims. 375 total patients in the primary four studies.
 - For safety considerations, six additional case series, all with mid-term follow-up were identified and three cost-effectiveness analyses were also included.
 - The evidence based technology assessment report identified 9 expert treatment guidelines and a national Medicare policy relating to spinal cord stimulation.
- *Other Information:* The committee also reviewed information provided by the state agencies, and public members; and heard comments from the evidence reviewer, HTA program, the public and agency medical directors.

2. Is the technology safe?

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.

- The evidence based technology assessment report includes evidence on several safety outcomes including device complications, revisions, other complications and side effects and mortality for SCS and in several time frames. Short-term (< 5 years) safety data were reported by three RCTs and one prospective cohort study; mid-term (5 – 10 years) safety data were reported by one RCT and six case series. No long-term safety data were available.
- *Revision:* the evidence based technology assessment report found three RCTs and one cohort study which reported short-term revision rates of SCS devices; one RCT and all six case series reported mid-term revision rates. Overall, short term revision rates ranged from 25% to 38% of patients; and mid-term revision rates ranged from 42% to 60% (not including 54% of patients undergoing pulse generator replacements due to battery life). No long term revision rates available.
 - *Total Removal:* short term total removal, reported as a subset of revisions occurred in 3% to 22% of patients due to infection, rejection, discomfort, or ineffective pain relief. Mid-term total removal rates ranged from 4% to 17% of patients.
- *Other SCS-related complications or side effects:* the evidence based technology assessment report found that complications or side effects ascribed to the SCS device were reported by two RCTs, one cohort study, and six case series and included dural punctures, amplitude by bodily movements; paresthesia in other body parts, pain, disturbed urination, lead fracture, loss of effect, infection.
 - Overall short-term complication rates ranged from 8-100% of patients. At two years follow-up, one RCT reported that side effects had occurred in 100% of available SCS patients; another RCT reported device-related complications not requiring revision in 14% of patients.
- *Mortality:* the evidence based technology assessment report found short-term mortality data from three RCTs and one prospective cohort study. Two deaths occurred in the SCS groups (2/139) though these were not directly attributed to SCS. No deaths occurred in the control groups (0/179). Mid-term mortality data were obtained from one RCT and three case-series and identified 2 deaths in SCS patients, though not directly attributed to SCS; one patient nearly died from complication following trial stimulation.

3. Is the technology effective?

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.

- The evidence based technology assessment report included three RCT's and one prospective cohort study for evidence about efficacy and effectiveness of SCS for treatment of neurological pain.
 - Efficacy studies included: one RCT *Kemler* (level 1) comparing SCS with physical therapy in 54 CRPS patients funded by Dutch Gov; and two RCTs (*Kumar* Level 1 and *North* Level 2) reported on 160 patients with FBSS comparing SCS and conventional medical management (CMM) to CMM alone, or compared to lumbar reoperation (both funded by Medtronic).

- Effectiveness studies included one prospective cohort study, *Turner* (Level 2) on effectiveness of SCS compared with Pain Clinic and Usual Care treatments in 159 FBSS patients with open workers' compensation claims (funded by State of Washington).
- In general, the efficacy studies reported improvements in the SCS patients over the control groups whereas the effectiveness study did not find improvements in the SCS patients over control groups.
- *Trial Design:* Overall, the internal validity of included studies was high; however, several limitations were noted, including the overall small patient sample of 375. Appropriate comparators are not a criterion used by the evidence based technology report to score the quality of the study, but were noted in the study limitations of several studies. Additionally, blinding is a criterion included in scoring the studies, but was not met by any of the studies.
 - *Comparators:* In *Kemler*, SCS plus PT was compared to PT, although the inclusion criteria required that patients be unresponsive to PT for six months to be eligible so SCS was compared to a treatment known to be ineffective. Similarly, in *North* SCS was compared to re-operation in patients diagnosed with failed back surgery syndrome. Finally, the SCS groups received SCS plus other treatments (e.g. PT, Medications, Chiropractic) which confounds the effect of SCS alone.
 - *Blinding:* Neither patients nor treatment providers were blinded, none of the trials included sham stimulation or surgery to address potential placebo effect.
- *Outcomes:* Patient oriented outcomes of interest include measures of pain relief, improved function, reduction of medication, quality of life, and patient satisfaction. The evidence based technology assessment report indicates many pain related outcomes are subjective, and considerable debate remains about clinically meaningful differences.
 - Reduction in pain is the most commonly reported outcome, and a greater than 50% reduction on a VAS pain intensity is commonly used to determine success, though more studies are needed to determine significance.
 - No information on determining clinically significant differences for QOL, patient satisfaction, functional improvement, or reduction of medication was included in the evidence report.
 - Most improvement is reported as a change from baseline
- *Composite Success score:* Two studies used a composite score of success:
 - *North* used a composite of pain relief of greater than 50% and patient satisfaction, the pain measure was not disclosed, patient satisfaction was measured by whether patients would go through treatment again. Of 19 SCS patients, 47% achieved success versus 12% of 26 reoperation patients over a mean of 2.9 years.
 - *Turner* used a composite of leg pain relief of greater than 50%, greater than 2 point improvement on Roland disability index, and less than daily opioid use. Less than 10% in any group, and no significant difference between SCS, pain clinic (PC), or usual care (UC) groups at any follow-up up to 24 months achieved success.
- *Pain Relief:* Studies reported on pain relief, usually using VAS scores (0-10pt pain scale) at baseline and follow up and looking for a greater than 50% improvement. Patients in the randomized SCS trials reported significant improved pain relief compared with those randomized to undergo control treatments in two RCTs with ≤ 2 year follow-up.
 - *Kemler* reported significantly improved VAS scores at 6 months (4.2 vs. 6.6) and 24 months (4.3 vs. 6.6) for SCS compared to PT alone, but no difference at 60 months (5.0 vs. 5.9).
 - *Kumar* reported more SCS patients 48% at 6 months and 47% at 24 months reported greater than 50% improvement of VAS compared to CMM patients of 9% at 6 months and 7% at 24 months achieving 50% improvement. Mean VAS scores for SCS were 3.99 compared to 6.66 for CMM.

- Turner reported that more patients in the SCS group achieved $\geq 50\%$ leg pain relief by six months (18% vs. 3%) than those in the UC group; but no difference between the SCS and PC group (15% vs. 5%). No differences were identified between any groups in the percentage of patients achieving leg pain relief of $\geq 50\%$ or at the 12- and 24-month follow-ups (range 0% to 10%).
- *Function:* The Oswestry Disability Index and Roland-Morris Disability Questionnaire were used to assess improvement in function in two studies.
 - Kumar found SCS group had significantly better Oswestry scores than those in the CMM group (Mean score of 57.4 vs. 55.2 at baseline and 44.9 vs. 56.1 at six months).
 - North reported no significant differences between the SCS and reoperation groups in the neurological status or ability to perform daily activities a mean of 2.9 years follow-up, however, raw data were not provided.
 - Turner reported no significant differences in either the Roland-Morris Disability Questionnaire (RDQ) score improvement of greater than 2 points or ability to perform daily tasks between treatment groups SCS 51%; PC 41%; UC 44% with mean scores of 18.1, 17.9, and 17.5.
- *Health-related quality of Life (HR-QoL):* Two trials reported no differences, while on trial reported better quality of life scores for SCS.
 - Kemler reported no difference in several QoL outcome measures between the SCS and physical therapy groups, including the mean percent change in quality of life at the 6- and 24- month follow-ups as well as the Nottingham Health Profile, EQ-5D (EuroQol-5D), and Self-Rating Depression Scale scores at five years.
 - Kumar reported that patients randomized to receive SCS had significantly better scores in seven of the eight SF-36 (Short-Form 36) outcome scales compared with those randomized to receive CMM at six months.
 - Turner reported no significant differences between treatment groups in SF-36 scores and work/disability status.
- *Additional Patient Satisfaction and Perceived Effect:* Several RCTs also reported patient satisfaction, generally using questions (non-validated instruments) to patients. One RCT reported that significantly more patients in the SCS group were satisfied with both their level of pain relief and with their treatment in general than those in the CMM group at six months follow-up. Another RCT incorporated patient satisfaction with pain relief into a composite outcome, “success”, which was reported above. Another RCT reported global perceived effect (GPE) scores. Significantly more patients in the SCS group reported GPE of “much improved” or “best ever” at both the 6- and 24- month follow-ups compared with the physical therapy group; however the differences between groups were no longer statistically significant by five years.
- *Medication Usage:* Several trials reported on pain medication changes.
 - Kumar reported no differences at six months between the SCS and CMM groups in the percentage of patients using opioids, non-steroidal anti-inflammatory medications, or antidepressants; however, significantly fewer SCS patients were taking anticonvulsants than those in the CMM group.
 - Other treatments: no differences between the SCS and CMM groups in the percentage of patients using all reported non-drug therapies (e.g., physical or psychological rehabilitation, acupuncture, or massage) except for TENS (transcutaneous electrical nerve stimulation), for which the rate of use was lower in SCS compared with CMM patients.
 - North reported significantly more patients in the SCS group were taking a stable or decreased dosage of opioids (versus baseline) than those in the reoperation group at a mean of 2.9 years follow-up.
 - Turner reported no significant differences for less than daily opioid usage between SCS, PC, and UC groups 21%, 32%, 34%.

4. Special Populations?

- The evidence based technology reported rated six small prognostic studies (four prospective and two retrospective studies). In general, very little evidence was found that suggests that any of the factors evaluated were associated with differential outcome following SCS. Prognostic factors included: age, sex, workers' compensation or other disability payments, duration of pain, pain intensity, time since first lumbar surgery, number of prior operations for pain, pain location, laterality of pain, allodnia or hyposthesia at baseline, McGill Pain Questionnaire, Minnesota Multiphasic Personality Inventory (MMPI) and mental health component.
- *Duration of Pain:* Two studies evaluated and found no relationship between duration of chronic pain and pain relief in the first year following SCS implantation. One study reported that CRPS patients with a longer duration of chronic pain had significant improvements in quality of life at nine months as measured by two (of eight) domains of the SF-36 outcome measure by multivariate analysis; however, no association was found between pain duration and GPE scores.
- *Workers' compensation or other disability payments:* One study found no difference in the percentage of patients who achieved at least 50% pain relief at three months between those receiving workers' compensation or other disability payments than those not under such programs.
- *Pain Intensity:* One study evaluated and found no association between the pain intensity at baseline and pain relief at one year.
- *Pain Location:* Four studies evaluated and found no association between pain location and pain relief at follow-up, though each study compared different locations. One study reported no association between hand versus foot pain with nine-month SF-36 or GPE scores; another study found no difference in a combination of everyday activities, neurological function, and medication use between patients with axial versus radicular pain.

5. Is the technology cost-effective?

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.

- The evidence based technology report included three economic evaluations; two were published economic evaluations of SCS compared with other interventions for pain and one was included as part of the recent HTA conducted by NICE in the UK.
 - The UK report found that there is some evidence that SCS is cost-effective at moderate (<\$20,000) incremental cost effectiveness ratio (ICER) levels compared with CMM or reoperation, and that SCS cost-effectiveness increases and may be dominant over time compared with control treatments (i.e., CMM or reoperation) assuming device longevity of 4 years and at least a 30% pain threshold criteria. However, the evidence based technology assessment report indicated that overall efficacy data is moderate and a key assumption of continued efficacy past 3 years is questionable, given the only RCT reporting pain 5-10 years after implantation. A further limitation is that only one study was conducted in a US setting.
- Washington State Agency utilization and cost information indicated rising utilization (except in L&I due to current non-coverage); costs of SCS of \$9.6M over 4 years (average of \$2.4 million per year and per treatment cost of \$29,000).

6. Medicare Decision and Expert Treatment Guidelines

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

- Centers for Medicare and Medicaid Services currently covers SCS under certain conditions based on a 1995 policy, with no evidence evaluation cited. Conditions include: SCS implantation is only used as a late or last resort for patients with chronic intractable pain; patients have undergone careful physical and psychological screening by a team of physicians; there has been a previous demonstration of pain relief with temporarily implanted electrodes; everything needed for the proper treatment and follow-up of the patient is available (i.e., facilities, equipment, professional and support personnel, etc); and SCS implantation employs percutaneous insertion of electrodes into the epidural space.
- Guidelines – a search of the core sources and relevant specialty groups identified nine guidelines for SCS (American Society of Anesthesiologist Task Force and the American Society of Regional Anesthesia and Pain Medicine, 2010; American Pain Society, 2009; Comprehensive evidence-based guidelines for interventional techniques in the management of chronic spinal pain, 2009; Institute for Clinical Systems Improvement, 2008; National Institute for Health and Clinical Excellence, 2008; American College of Occupational and Environmental Medicine, 2007; European Federation of Neurological Societies, 2007; Reflex Sympathetic Dystrophy Syndrome Association, 2006; and Evidence-based clinical practice guidelines, 2005
 - Five guidelines recommend use for various pain treatments citing evidence; two guidelines indicate SCS may be considered citing weak or equivocal evidence; and two guidelines do not recommend use based on insufficient quality evidence.

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 Spinal Cord Stimulation has been collected and summarized.

- Spinal Cord Stimulation (SCS) is an alternative treatment proposed for patients with chronic neuropathic pain who have not responded to conventional therapies such as medication, physical and/or psychological therapy, and in some case, reoperation.
- Current best evidence is available primarily from four trials on 375 patients; which are rated at a Level 1 or 2 (good quality), which is a better level of evidence than some interventions. However, total patient sample size is small, comparators were weak or inappropriate, reported outcomes are mostly subjective and not consistently reported, industry funding and management may have an impact, and no trial included a sham stimulation/procedure arm. The overall body of evidence was inconsistent, with several trials showing benefits on some outcomes at generally shorter follow up periods and others showing no difference.
- SCS is an implanted, long term treatment, but no evidence exists on either long term efficacy or safety.

2. Is it safe?

The committee concludes that the comprehensive evidence indicates that Spinal Cord Stimulation is less safe than alternative treatments. Key factors to the committee's conclusion included:

- The committee agreed that SCS is less safe than alternatives, is an invasive procedure, and has many adverse events. While conventional medical management is not invasive, so would generally have a lower risk profile, reoperation is also a comparator and had less complications. SCS device related complications can be serious and include dural punctures, amplitude by bodily movements; paresthesia in other body parts, pain, disturbed urination, lead fracture, loss of effect, infection.
- The committee agreed that safety was a significant factor: the number of trial reported complications ranged from 8 to 100%. Device related complication requiring revision ranged from 25% to 38% of patients in short term and 42% to 60% in up to 5 years (not including 54% of patients undergoing pulse generator replacements due to battery life).
- The committee agreed that there were currently no reported mortality rates, but that the FDA data was not available and the small sample size is likely underpowered to detect.
- The committee agreed that the removal rate could be considered an efficacy or safety issue, but the rates ranging from 4% to 17% were concerning, especially considering that trial stimulation is done first on all patients.

3. Is it effective?

The majority of the committee concludes that the comprehensive evidence about Spinal Cord Stimulation effectiveness is unproven.

- The committee agreed that the studies had serious limitations in design, low patient sample sizes, and weak or inadequate comparators. Additionally, placebo effects of a new intervention for patients with chronic pain who have already failed multiple therapies is a serious concern and no study involved sham stimulation or procedures and outcome measures were generally subjective.
- The committee found that evidence overall on important patient outcomes was limited. For all outcomes, there is no evidence of longer term improvement, particularly important when there are significant risks (including 1/3 revision and high removal rate) and the device is intended for permanent implant.
- Given the serious limitations of the studies, the committee agreed that, at best, weak evidence exists that SCS may provide temporary improvement of pain in some patients, but there is no evidence of mid or long term pain improvement.
- While pain is a critical patient outcome, evidence about other important patient outcomes was either not available or not consistent with the pain findings.
 - For instance, for reduction in pain medication in short term: Kumar and Turner found no difference, while North found SCS patients did have reduction.
 - For functional improvements, 1 trial found short term functional improvement, but 2 others did not; and there was no reliable evidence of functional improvement at mid (or long) term.
- For all other outcomes, including improvement in quality of life, there is no reliable evidence of effect.

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

The committee agreed that no compelling evidence exists to differentiate sub groups or special populations.

- The committee agreed with the evidence based report that there is inadequate evidence to identify characteristics that either enhance or reduce the efficacy of SCS such as age, sex, workers' compensation or other disability payments, duration of pain, pain intensity, time since first lumbar surgery, number of prior operations for pain, pain location, laterality of pain,

allodynia or hyposthesia at baseline, McGill Pain Questionnaire or the Minnesota Multiphasic Personality Inventory (MMPI).

5. Is it cost-effective?

The committee concludes that SCS is unproven to be cost effective.

- The committee agreed that the cost of SCS is substantial, averaging \$27,000 per patient.
- The committee agreed that overall value cannot be ascertained without evidence of net benefit of effectiveness and reduced harm. Reliable cost-effectiveness analysis cannot be performed.

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, and agency and state utilization information. The committee concluded that the current evidence on Spinal Cord Stimulation demonstrates that there isn't sufficient evidence to cover the use of Spinal Cord Stimulation for chronic neuropathic pain. 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. Based on these findings, the committee voted 8 to 1 to not cover with Spinal Cord Stimulation.

The committee reviewed the Clinical guidelines and Medicare decision. The Medicare decision was did not cite evidence and was decided prior to any of the studies reviewed by the committee. The guidelines recommendations conflict and not all have reviewed the latest trials included in this report.

Health Technology Clinical Committee Authority

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