Washington State Health Care Authority, HTA Program
Key Questions and Background
Spinal Cord Stimulator

Introduction

HTA has selected Spinal Cord Stimulators for review. An independent vendor will systematically review the available evidence on the safety, efficacy, and cost-effectiveness. HTA posted the topic and gathered public input about available evidence. Key questions guide the development of the evidence report. They are posted for public review and comment. HTA seeks to identify the appropriate topics (e.g. population, indications, comparators, outcomes, policy considerations) to address the statutory elements of evidence on safety, efficacy, and cost effectiveness relevant to coverage determinations.

Key Questions

Spinal cord stimulators are surgically implanted devices used to deliver electrical stimulation to the spinal cord to treat pain. When used in adult patients with chronic pain (neuropathic) who have failed alternative therapies:

1. What is the evidence of efficacy and effectiveness of spinal cord stimulation? Including consideration of:
    a. Short-term and long-term outcomes
    b. Impact on Function, Pain, quality of life
    c. Other reported measures including: use of pain medications and opiods, return to work; intensity and duration of use

2. What is the evidence of the safety of spinal cord stimulation? Including consideration of:
    a. Adverse events type and frequency (mortality, major morbidity, other)
    b. Revision and removal rates including loss of paresthesia (if not addressed in efficacy)
    c. Infections
    d. Lead migration
    e. Technical malfunctions (e.g., early battery failure, broken leads)

3. What is the evidence that spinal cord stimulation has differential efficacy or safety issues in sub populations? Including consideration of:
    a. Gender
    b. Age
    c. Psychological or psychosocial co-morbidities
    d. Diagnosis or pain type
    e. Other patient characteristics or evidence based patient selection criteria
    f. Provider type, setting or other provider characteristics
    g. Health care system type, including worker's compensation, Medicaid, state employees

4. What evidence of cost implications and cost-effectiveness of spinal cord stimulators? Including consideration of:
    a. Costs (direct and indirect) in short term and over expected duration of use
    b. Replacement

Technology Background

Disease: Chronic pain from conditions such as chronic leg or back pain resulting from failed back surgery syndrome (FBSS), severe nerve related pain or numbness; complex regional pain syndrome (CRPS or reflex sympathetic dystrophy).

Treatments: Chronic pain treatment may include pharmacological treatment, physical therapy, coping skills, antidepressants, cognitive behavioral therapy and supported self-management, to surgical treatment. Treatment strategies generally begin with the least invasive and low risk interventions and progress if the treatments are not effective. Treatment often involves a combination of interventions.

Technology: Spinal Cord Stimulation (SCS) involves the administration of electrical impulses in the spinal cord via an implanted pulse generator. Significant questions remain about the safety, efficacy and effectiveness (particularly long term), and the cost effectiveness of SCS.

Public Comment and Response

HTA received five timely public comments, four of which addressed the key questions and their relevance to guide the development of the evidence report; and input from the technology assessment center. HTA reviewed the public comments, consulted technology assessment centers, and gathered follow up information from the nominating agencies. A summary of the input and modification to key questions is below.

Overall topic/other information: The literature base for use of SCS for treatment of ischemic pain was not initially consulted by the evidence vendor, is separate, and represents a substantial increase in the report and would likely result in essentially separate sections or reports on the two pain types. Agencies primarily have experience with, and the concerns raised primarily related to, neuropathic not ischemic pain. The population was modified to remove ischemic. The questions overall were modified to make clearer that the list of subcategories are examples of considerations that effect the key question. An additional note: inclusion of outcomes do not set a threshold for decision, the weight and relevance of outcomes are judged by the clinical committee. Summary of additional comments by question follows.

Question 1: Three commenters felt the subcategories in question 1 should be modified primarily to exclude “return to work” as an outcome on the basis that it was not a relevant outcome; and to expand the pain medications listed.

The pain medication is expanded. Return to work is not excluded as an outcome. This outcome is listed in examples of “other measures”; not within the primary listing of pain, function and quality of life in acknowledgement of some of the limitations mentioned. However, return to work is a patient centered measure reported in clinical trials and addressed as an outcome in several previous HTA reports. It is especially relevant to the effectiveness of the therapy in the context of the purpose of this report which is to inform health purchasing decisions that directly impact public payers whose core missions include returning or enabling their populations to work. The comments related to the limitations of return to work outcomes (e.g. quality, confounding) are acknowledged and are pertinent to the discussion in the evidence report, whereas the overall weight and relevance will be a judgment of the clinical committee, which can be informed by public comment.

Question 2: One commenter requested a comparative analysis with other conventional treatments’ safety. A comprehensive comparative analysis (effectiveness or safety) is beyond the scope of a health technology assessment and outside the scope of the health policy decision that the evidence review is

intended to inform (a decision on SCS, not on comparative coverage for all chronic pain therapies). Relevant context and trial information about safety and adverse events of the technology and utilized comparators, where appropriate, are included in reports.

Question 3: Four commenters had interrelated requests that the question on evidence of differential effect in subpopulations be reformulated to address patient selection and the subcategory of "worker's compensation" be eliminated. Consideration of evidence based patient selection criteria is added as a subcategory and payer based categories, including worker's compensation are reworked but not excluded.

Patient selection criteria alone are not an appropriate replacement for the current question which asks broadly about evidence of differential effect or harm. Patient selection criteria presumes efficacy and effectiveness and a net benefit for at least a specified group and is a targeted question most relevant to clinical guideline development. While the current question should already encompass evidence which would also form the basis for patient selection criteria, the subcategory is added.

The current inclusion of worker's compensation as a consideration under subpopulation generated the most comments based on an assertion that payer source is either not appropriate, confounds effectiveness or blends with patient characteristics. For patient selection criteria alone, these comments may have more relevance, but as explained above, this key question is based on a broader legislative requirement and policy issue about evidence of differential effect. The inclusion of payer based categories is common in research as well assessments (e.g. Medicare or Medicaid beneficiaries). This is especially relevant in evidence reviews designed to assist in health purchasing decisions and for issues of generalizability or effectiveness where impact of variables in the "real world" are studied. To the issue of "blending", patient categorization for research purposes does not have to be mutually exclusive, and categorization based on exogenous factors may actually reduce confounding. Further, the subcategories are examples; if evidence is found related to any of the subcategories, the evidence report can distinguish as appropriate. Evidence of differential effects, whether based on demographics, clinical measures, employer or payer categories, or other subpopulation descriptors are valued information, from which the committee can determine relevance or weight of the evidence to its decision.

Question 4: One commenter requested that the direct costs subcategory include indirect costs. Subcategory updated to include both.