



Health Technology Clinical Committee

Date: May 18, 2007

Time: 8:00 am – 4:30 pm

Location: Hilton Seattle Airport and Conference Center
 17620 Pacific Highway South
 Seattle, WA 98188

D*R*A*F*T

HTCC MINUTES

Members Present: Brian Budenholzer; C. Craig Blackmore; Michael Myint; Carson Odegard; Daniel Abrahamson; Louise Kaplan; Richard Phillips; Michelle Simon and Michael Souter.

Members Absent: Lydia Bartholomew

HTCC Formal Action

- ✓ **Call to Order:** Brian Budenholzer, Chair, called the meeting to order at 8:30 a.m. Sufficient members were present to constitute a quorum.
- ✓ **Bylaw Ratification:** Leah Hole-Curry, HTA Program Director, presented the draft Bylaws circulated to committee members previously and reported that no committee comments were received. The Bylaws are approved by the HCA Administrator and are presented for ratification by the Chair as required by WAC. The Chair called for discussion or objection, and received none; and noted that Bylaws could be amended later if necessary.
 - *Outcome:* The Chair ratified the HTCC Bylaws.
- ✓ **Upright/Positional MRI:** The HTCC reviewed and considered the Upright/Positional MRI technology assessment report, information provided by the Administrator, agency comments, the technology assessment center's presentation; and invited public testimony. The committee considered all the evidence and has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.
 - *Outcome:* The HTCC unanimously voted that the evidence is insufficient to conclude that the Upright/Positional MRI (uMRI) technology is safe, efficacious, and cost-effective; therefore, the use of the Upright/Positional MRI is not covered.

For presentation and discussion details, please see following pages

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HTCC MEETING TOPICS, PRESENTATION, DISCUSSION

Agenda Item: Welcome & Introductions

Brian Budenholzer, Committee Chair, and Leah Hole-Curry, HTA Program Director, opened the meeting with an overview of the agenda, meeting purpose and introductions.

- ✓ The Health Technology Clinical Committee (HTCC) met on May 18, 2007, to discuss the evidence of the Upright/Positional MRI health technology; hear the Technology Assessment Center's presentation and public comment; ratify the committee bylaws; and determine a coverage decision based on the evidence regarding the technology's safety, effectiveness and cost-effectiveness.
- ✓ The clinical committee meets and will hear public testimony, see presentation of report, and make coverage decision based on evidence. Clinical committee members make coverage determinations for five participating agencies. Their decision outlines whether benefit should be included as a covered benefit, and if so, the circumstances under which state agencies should reimburse. Coverage and reimbursement decision should be consistent with National Medicare Decisions and guidelines.
 - *Outcome:* Informational context was provided to the committee panel

Agenda Item: HTA Program Overview

Leah Hole-Curry, HTA Program Director, presented an HTA program and process overview.

- ✓ HTA Program Background and purpose:
 - Governor Gregoire's 2006 five-point health strategy created the Health Technology Assessment (HTA) Program with the Health Care Authority (HCA). HTA contracts for reviews of evidence of "health technologies." Report used by an independent clinical committee (HTCC) of eleven practicing health care providers. Decisions apply to the Health Care Authority, Labor and Industries, and Department of Social and Health Services. The Department of Corrections and Veterans Affairs are voluntarily participating.
 - The purpose of the committee is to make coverage determinations for the participating agencies (Health Care Authority; Department of Social and Health Services; and Labor and Industries) based on a health technology assessment presented by Spectrum Research, Inc. that reviews the scientific evidence of the relative safety, efficacy, and cost; information from any special advisory groups; and their professional knowledge and expertise.
- ✓ HTA Product:
 - Achieve better health by paying for technologies that work. Maintain an open and transparent process; eliminate bias; promote consistency; and remain flexible by reviewing evidence regularly to ensure updated information is included.

- Key focus questions: Is it safe and more effective? Is it equally effective, but safer? Is it equally effective and safe, but more cost effective?
 - *Note:* Key questions posted on HTA website: <http://www.hta.hca.wa.gov/assessment/index.shtml>
- ✓ Coverage Determination Process:
 - As defined in the WAC when making a coverage determination, committee members shall review and consider the health technology assessment. The committee may also consider other information it deems relevant, including other information provided by the administrator, reports and/or testimony from an advisory group, and submission or comments from the public.
 - HCA Administrator selects technology → Vendor produce Technology Assessment Report → Clinical committee makes coverage determination → Agencies implement decision (unless statutory conflict).
 - The committee shall give the greatest weight to the evidence determined, based on objective factors, to be the most valid and reliable, considering the nature and source of the evidence, the empirical characteristic of the studies or trials upon which the evidence is based, and the consistency of the outcome with comparable studies. The committee may also consider additional evidentiary valuation factors such as recency (date of information); relevance (the applicability of the information to the key questions presented or participating agency programs and clients); and bias (presence of conflict of interest or political considerations).
 - *Outcome:* Informational context provided regarding HTA program, process overview and meeting purpose.

Agenda Item: Topic Selection and Introduction

David Flum, M.D., HTA Clinical Consultant introduced the technology selection process and the uMRI topic.

- ✓ Technology Selection Process: The Administrator, in consultation with participating agencies and the committee, shall select the health technologies to be reviewed by the committee under RCW 70.14.110. Up to six technologies may be selected for review in the first year, and up to eight may be selected in the second year. In making the selection, priority shall be given to any technology for which: (a) There are concerns about its safety, efficacy, or cost-effectiveness, especially relative to existing alternatives, or significant variations in its use; (b) Actual or expected state expenditures are high, due to demand for the technology, its cost, or both; and (c) There is adequate evidence available to conduct the complete review.
 - Primary Criteria
 - Patient Harm or Safety Concerns
 - Concerns about therapeutic efficacy or diagnostic accuracy and appropriateness of outcomes for patients

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- Cost impact for state purchasing agencies
 - Secondary Criteria
 - Number of persons affected
 - Severity of condition
 - Policy related urgency / diffusion concern
 - Potential or observed variation in care
 - Special populations or ethical concerns
 - ✓ Upright and positional MRI (uMRI) is a magnetic resonance imaging test designed to be performed with patients in weight bearing or different positions, (e.g. upright, sitting, standing, flexed or extended). Current alternative imaging tests used to diagnose spinal and other joint conditions are a regular MRI (lying down), Computerized Tomography (CT) myelogram, regular or flexion and extension radiographs (x-rays), and discography.
 - ✓ The potential advantage of a uMRI is that the weight bearing or positional images may capture additional findings. Also, the open MRI equipment may improve patient compliance by combating the claustrophobia of traditional MRI scanners and enhance patient comfort. Potential disadvantages are that weight bearing and different positions can cause patient pain and result in an inability to complete the test; and the magnet strength, which determines image quality, of a uMRI is lower (0.6T for uMRI compared to a standard MRI range of 1.0T to 3.0T).
 - *Outcome:* Informational context for technology under consideration.

Agenda Item: Technology Assessment Presentation

Andrea Skelly, Director of Evidence Based Practice Division, of Spectrum Research Inc. presented a summary of the technology assessment report.

- ✓ The accuracy of a diagnostic test consists of two general components: the accuracy of classifying patients with respect to their disease status (validity), and the degree to which repeated measures yield the same results (reliability). Diagnostic tests should only be performed if it leads to the use of interventions that are likely to improve patient outcomes or it prevents the use of interventions that are not likely to improve outcomes.
- ✓ No systematic review and critique of evidence quality has been done for the Upright/Positional MRI (uMRI) used in the evaluation of the spine and extra-spinal joints.
 - This assessment included a systematic search of the published literature on the use of uMRI for spinal conditions as well as extra-spinal joint conditions. The primary aim of this assessment was to take an evidence-based approach to systematically review and analyze research evidence comparing the use of uMRI with currently available diagnostic tests for the following musculoskeletal conditions; degenerative spondylolisthesis, spinal or foraminal stenosis, radicular pain, non-

specific back pain and extra-spinal joint pain/function loss. Secondary aims were to critically summarize published formal economic or cost evaluations.

✓ **Assessment of Overall Strength of Evidence**

- Standardized abstraction forms and guidelines were used to determine the Level of Evidence (LoE) for each study included in the technology assessment. LoE I studies represent the highest quality and LoE IV the lowest, based on factors considered most likely to induce bias. After the LoE for each individual study was assessed and the body of evidence for a given topic was evaluated, the overall strength of evidence for that topic was determined based on the quality of studies as well as consistency of effect estimates and the likely impact of additional research on the topic. A high SoE (i.e., SoE I) reflects a high level of confidence that estimates of relevant parameters are stable and unlikely to change with additional research where as a very low SoE (i.e., SoE IV) indicates that estimates are likely unstable and the effect of additional research on them is uncertain.
- Based on systematic review of the literature, few studies (n=6 of 136) met the inclusion criteria (based on the key questions) and quality of literature available to address the questions was poor. Significant methodological shortcomings that may bias study results were present in all of the included studies and included failure to include a broad spectrum of patients, verification bias and interpretation bias. Sample sizes were small and in general, protocols were not methodologically rigorous.
 - There is limited evidence to suggest that uMRI provides similar diagnostic information compared with rMRI with respect to disc pathology and foraminal stenosis of the lumbar spine. The evidence for concordance between rMRI and uMRI is very low with respect to cervical disc herniation, lumbar nerve root compromise, and spondylolisthesis.
 - The two studies included in the technology assessment comparing uMRI with another method for evaluation of extra-spinal conditions were somewhat stronger methodologically; however, both suffered from small sample sizes (<20 patients). There were no reliability studies evaluating extra-spinal joint conditions. No evidence is available either to suggest uMRI images are contributory towards the identification of Morton neuroma or shoulder instability compared with existing diagnostic tests.
 - No studies validated the diagnostic ability of uMRI in the evaluation of the hip, knee or ankle were found.
 - There is no evidence that uMRI is reliable in detecting degenerative spondylolisthesis, lateral recess stenosis, radicular pain or non-specific spine pain.
 - No published reports were found that address the diagnostic or therapeutic impact of uMRI on spinal or extra-spinal conditions overall or with respect to specific evaluation of acute or sub-acute/delayed

conditions. While several small studies describing changes in anatomy or additional finding with position or loading may point to the potential of uMRI to add meaningful diagnostic information that may impact diagnostic and therapeutic decision making, they do not provide sufficient evidence with respect to uMRI's ability to enhance patient outcomes.

Evidence-Based Summary and Conclusions

- ✓ No studies which assessed the validity (diagnostic accuracy) of uMRI were found. This is the most significant limitation of the current literature since, without methodologically rigorous validation studies comparing uMRI to an appropriate “gold” or reference standard, characteristics which describe diagnostic accuracy, such as sensitivity, specificity and predictive values or likelihood ratios cannot be determined with any confidence. Furthermore, without a reasonably solid estimate of diagnostic accuracy, meaningful evaluation of the diagnostic and therapeutic impact of uMRI for various conditions or disease states may not be feasible.
- ✓ Well designed, adequately powered, methodologically rigorous validation (diagnostic accuracy) and reliability studies are needed in order to assess the clinical utility of uMRI for the evaluation of spinal and extra-spinal conditions. Studies designed to determine correlation between uMRI findings and patient symptoms and outcomes are needed.
 - *Outcome:* Information of evidence findings provided regarding the uMRI

Agenda Item: Public and Invited Comments

No public members requested to make a public comment.

Agenda Item: HTCC Decision Tool

Brian Budenholzer, Chair introduced the diagnostic decision worksheet to be used by the committee in evaluating the evidence of the technologies' safety, efficacy, and cost effectiveness. The tool was a combination of efforts based on staff, committee input and Dr. Budenholzer's research. Committee members agreed that this worksheet would be of assistance to them in their discussion and evaluation of the technology.

Agenda Item: HTCC Upright/Positional MRI Technology Discussion

Brian Budenholzer, Committee Chair, led discussion of the evidence related to the safety, efficacy, and cost effectiveness of the uMRI.

- ✓ The HTCC reviewed and considered the Upright/Positional MRI technology assessment report, information provided by the Administrator, agency comments, the technology assessment center's presentation; and invited public testimony. The committee considered all the evidence and has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

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- ✓ The HTCC reviewed and considered the Upright/Positional MRI technology assessment report, information provided by the Administrator, and invited public and agency comments. Committee members were confident that scientific evidence confirms that the technology is safe because the technology is comparable to other MRI tests and administration of the test is unlikely to cause a significant adverse health effect. Committee members found that there was insufficient scientific evidence to make any conclusions about uMRI's effectiveness, including whether uMRI: accurately identifies an appropriate diagnosis; can safely and effectively replace other tests; and results in equivalent or better diagnostic or therapeutic outcomes.
 - ✓ Taking safety and effectiveness data together, the committee found that there was insufficient evidence to conclude whether the use of uMRI would result in a less, equivalent, or more health benefit. Most compelling:
 - Technology is ten years old, but no accuracy studies and very few reliability studies
 - Of the studies available, most were poor quality and sample sizes were very small
 - Image quality is lower and some evidence of higher percentage of individuals not being able to complete the test due to pain from positioning
 - Other tests are currently available for diagnosing same conditions, even though it was noted that those tests might also have limitations
 - One study that was of higher quality raised the possibility that uMRI might be less beneficial due to decreased findings
 - Most other payers do not cover, though one payer does
 - There are no evidence based clinical guidelines addressing appropriate uMRI usage
 - ✓ Committee members found that there were no independent cost analysis, but the cost of use of the uMRI would be higher based on manufacturer reported costs of \$1450 for a single image with additional images costs ranging from \$350 to \$1200.
 - *Outcome:* The HTCC unanimously voted that the evidence is insufficient to conclude that the uMRI technology is safe, efficacious, and cost-effective; therefore, the use of the Upright/Positional MRI is not covered.