

Health Technology Clinical Committee

Date: March 20, 2009

Time: 3:00 pm – 5:00 pm

Teleconference Bridge: 1-309-946-5000 Access Code: 9461464

Final Adoption: May 8, 2009

FINAL HTCC MINUTES

Members Present: Brian Budenholzer; Michelle Simon; Michael Souter; Louise Kaplan; Richard Phillips and Michael Myint.

Members Absent: C. Craig Blackmore; Carson Odegard and Jay Klarnett.

HTCC FORMAL ACTION

1. **Call to Order:** Dr. Budenholzer, Chair, called the meeting to order at 3:07 p.m. Sufficient members were present to constitute a quorum.
2. **November 14, 2008 Minutes:** Chair referred members to the draft minutes and called for a motion and discussion.
 - *Outcome:* The committee unanimously approved the November 14, 2008 minutes.
3. **Artificial Disc Replacement Findings and Decision:** Chair referred members to the updated draft findings and decision and called for a motion and discussion.
 - *Outcome:* The committee unanimously approved the Artificial Disc Replacement updated findings and decision document.
4. **Computed Tomographic Angiography Findings and Decision:** Chair referred members to the draft findings and decision and called for a motion and discussion.
 - *Outcome:* The committee unanimously approved the Computed Tomographic Angiography findings and decision document with a condition. Approval is subject to a review by the Chair of any additional comments received through March 27th.
 - If editorial changes are needed the Chair will update and finalize the document. If comments raise the need for full committee review or major changes are needed, the document and comments will be reviewed by the committee at the next public meeting.
5. **Upright MRI Re-Review Request:** Chair referred members to a request to re-review Upright MRI, heard requestor's testimony, and called for a motion and discussion.
 - *Outcome:* The committee unanimously agreed that new evidence was not sufficient to necessitate a re-review of the Upright MRI in the 2009 round.
6. **Retreat Feedback:** The Chair summarized feedback from committee members received at retreat and proposed changes to the discretionary meeting operations and structure in order to gather comments from the committee members before finalizing his decision.

Version officially adopted on May 8, 2009

- **Outcome:** Clinical Expert – Pilot having a clinical expert at the next two clinical committee public meetings.
- **Outcome:** Public Comment – Continue three minutes for those individuals who show up the day of and streamline stakeholder comments to five minutes each within overall 45 minute time frame. The Chair will work with HTA staff to update the public comment guide.
- **Outcome:** Receipt of Materials at Meeting – Committee should receive all meeting materials one week prior to the public meeting. And all publicly submitted materials need to be submitted to the vendor to be integrated into the technology assessment evidence report. The committee Chair directed HTA staff to update the public comment and meeting guide to indicate this.

SUMMARY OF HTCC MEETING TOPICS, PRESENTATION, AND DISCUSSION

Agenda Item: Welcome & Opening Remarks

The Health Technology Clinical Committee (HTCC) met on March 20, 2009. The primary topics for discussion include:

- ✓ Review and adoption of the November 14, 2008 public meeting minutes.
- ✓ Review and adoption of the Artificial Disc Replacement Findings & Decision.
- ✓ Review and adoption of the Computed Tomographic Angiography Findings & Decision.
- ✓ Discussion regarding the Upright MRI Re-review request.
- ✓ Retreat discussion and feedback.

Agenda Item: November 2008 Meeting Minutes

Dr. Brian Budenholzer, Committee Chair, presented the draft minutes from the November 2008 meeting. The minutes were drafted by HTA staff and circulated to committee members for comments. No committee comments were received. Chair referred members to the November minutes and called for further discussion, or a motion to approve.

- ✓ Motion and second to approve minutes made. No further discussion
- ✓ Minutes were unanimously approved

Agenda Item: Artificial Disc Replacement Findings & Decision

Chair referred committee members to the updated draft findings and decision for artificial disc replacement. Staff (HTA director) reviewed the updated draft Findings & Decision for Artificial Disc Replacement: the document was drafted by HTA staff; circulated to committee members and posted for public comments on December 12th, 2008 for a three week public comment period ending January 2nd, 2009. No committee comments received, 1 agency comment, 1 industry comment and 1 association comment were received by the program. Primary comments were to separate Cervical and Lumbar ADR and remove access to structured intensive multidisciplinary program from conditions for Cervical ADR because it wasn't included in the Cervical ADR discussion by committee at the public meeting. HTA Staff consulted with chair and updated draft to reflect public comments consistent with record and clarity. Chair, referred members to the draft Findings & Decision for Artificial Disc Replacement, and called for further discussion, or a motion to approve.

- ✓ Motion and second to approve document made. Discussion ensued
- ✓ Artificial Disc Replacement Findings & Decision were unanimously approved

Agenda Item: Cardiac Computed Tomographic Angiography Findings & Decision

Chair referred committee members to the draft findings for Computed Tomographic Angiography. Staff reviewed the draft Findings & Decision for CCTA: the document was drafted by HTA staff; circulated to committee members and posted for public comments on March 13th, 2009 for a two week comment period ending March 27th, 2009. No committee comments were received. Staff also conducted additional outreach efforts to individuals who commented at the November public meeting and during the draft evidence report public comment period. No public comments received. Staff noted that the public comment period ends after the meeting date, and normally would occur prior to meeting.

Dr. Budenholzer proposed a conditional approval of the draft Findings & Decision, pending the completion of the full public comment period. Chair would review any public comments received after March 20th, 2009, and would accept minor edit changes. However, if comments raise the need for full committee review or need for large changes the draft Findings & Decision and comments would be re-presented at the next public meeting. Committee discussed document and proposal. Chair referred members to the draft Findings & Decision for Cardiac Computed Tomographic Angiography and called for further discussion, or a motion to approve based on the provisions discussed and set.

- ✓ Motion and second to approve document, with condition made. Discussion ensued
- ✓ Cardiac CTA Findings & Decision were unanimously approved with condition

Agenda Item: Upright MRI Re-review Request

Chair referred to request for re-review submitted by Attorney Robert Battles, representing Capital Imaging, LLC. Chair noted this is the first direct request for topic review or re-review to committee and explained that the decision before the committee today was whether a re-review should be commissioned, not a discussion about changing the previous Upright MRI coverage decision itself. HTA staff referenced the meeting package materials and brought to the committee's attention the Upright MRI request and the HTA prepared re-review summary. Additionally, three UCLA study related documents were submitted by the requester and included in the meeting package materials. HTA Staff summarized background: May 2007, the clinical committee determined insufficient evidence existed to approve coverage, and referenced specifics of coverage decision. In September 2008, the HTA program published the 2009 topic selection and two re-review topics and circulated to committee for comments. A PUB MED scan was done on Upright MRI by the HTA clinical consultant, and no significant new evidence and/or concerns were identified by the search, no issues raised by the Agency Medical Directors. One public comment from Mr. Battles' office was received indicating a re-review should be granted and including studies referenced in the committee's material. The HCA Administrator reviewed the request for re-review and did not find sufficient new evidence to merit a re-review, and did not select the topic for re-review. The requester then petitioned the clinical committee for committee action.

The Chair opened the meeting to the requestor for a ten minute presentation led by Mr. Robert Battles. The requestor presented a rationale in support of the re-review, as outlined in the letter of request and referenced the three UCLA articles included in the committee meeting package as well as provided new information on the cost charged by a facility and new CMS issued codes and charges.

Committee discussed the petition, review of studies submitted, views on evidence, and asked follow-up questions to the requestors. Highlights of discussion included: level of evidence presented is not substantially different or inconsistent with previously reviewed trials; evidence is low quality and does not focus on patient or therapy alteration outcomes; updated cost information needs to be submitted in advance and did not address issue of expense from multiple views. Chair called for any further discussion, or a motion. Staff recommended amendment to motion to clarify that the motion for re-review is for the 2009 selection (further re-review cycles occurring at least every 18 months may produce different evidence and outcomes).

- ✓ Motion and second made. Discussion ensued.
- ✓ No re-review of Upright MRI for 2009 cycle approved unanimously.

Agenda Item: Retreat Feedback

Chair noted that he appreciated the committee's thoughts and feedback at the February 2009 retreat. Based on the discussions held at the retreat, the Chair proposed a few different approaches to the current meeting structure and requested committee perspectives prior to finalizing any decisions.

Clinical Expert – Chair proposed a pilot of having a clinical expert available at the next two public meetings, with roles and responsibilities outlines. Within budgetary constraints, the best option would be for the technology assessment vendor to provide a clinical expert (e.g. peer reviewer from the evidence report) to be available; otherwise, having the HTA program’s clinical consultant find a clinical expert. Committee clarified that it would be inappropriate for the clinical expert to be part of the decision-making process. Clinical expert should only be directed questions, and only at the general discussion phase, not when coverage decision is being made. Leah Hole-Curry, HTA Director, expressed that this meeting structure request are not by-law changes and can be made at the Chair’s discretion.

- ✓ Outcome: Committee unanimously agreed to pilot the clinical expert for the next two public meetings. HTA staff will work with Chair on process and technical and financial feasibility.

Public Comment – Chair provided background regarding how the committee has handled public comments thus far. Leah Hole-Curry, HTA Director, provided a detailed summary on how the program handles public comments submittals and allocation on time.

- ✓ Outcome: Committee unanimously agreed to continue to allow 45 minutes for public comments. Three minutes will be allotted for individuals who show up the day of the public meeting, and five minutes will be allotted to stakeholders who request time in advance of the public meeting.
- ✓ Outcome: HTA staff will work with Chair to update the public comment guide to reflect these changes.

Receipt of Materials at Meeting – Chair commented on the value of receiving information from the public (materials), but stressed the need to do it in a timely manner and through the evidence based evaluation process. Chair stressed that the program needs to submit meeting materials to the committee at least one week in advance of the public meeting. Chair stressed that stakeholders needed to use the program process in submitting materials to the committee, so it can be integrated into the technology evidence report. The process for any “last minute – late breaking evidence” is the re-review process.

- ✓ Outcome: Committee unanimously agreed that receipt of committee materials needs to be submitted one week prior to the public meeting. The committee unanimously agreed that all stakeholder materials need to be submitted to the program to be included in the technology evidence report. No materials will be accepted by the committee at the public meeting.
- ✓ Outcome: HTA staff will work with Chair to update the public comment and meeting guide to reflect these changes.