

Health Technology Assessment Program Review

The HTA program completed its first full year and initiated a quality assessment of the program and its processes in spring 2007. The program gathered feedback from its committee, stakeholders, agencies, legislators, and legislative and governor staff. This report summarizes the program's goals, the feedback received, and identifies areas of program change or proposed change.

Background: New innovations in medicine, even in the last ten years, have improved the health and lives of patients, yet they have come at a high cost in terms of health, safety, and affordability. Health care spending and costs are rising dramatically, but patients in the U.S. are not getting healthier nor using health care that is available, recommended, and proven to work. Medical products and treatments are introduced without independent, scientific evidence about whether they are safe, effective, and provide benefits that are better than existing alternatives. The information age has compounded the problem – there is a flood of information, but doctors and patients don't have the tools or the time to sort through it all. This overload of information, combined with a lack of tools to understand or test the information's reliability has led many health care professionals to turn to evidence-based medicine to identify best practices in treatment and diagnosis as well as payment and coverage decisions.

HTA Vision

Achieve better health care outcomes for enrollees and beneficiaries of state programs by paying for proven health technologies that work.

HTA Mission

Base coverage on evidence that a medical procedure, device, or test is safe, effective, and provides value.

HTA Goals

- Safer health care by relying on scientific evidence and a committee of practicing clinicians
- More consistent state agency coverage decisions
- More cost-effective state purchased health care by covering what is proven to work
- More transparent coverage decisions by publishing information, criteria, and rationale and holding public meetings

HTA Structural Elements

- Public Engagement and Transparency
- State Agency Coordination and Support
- Technology Selection and Evidence Review
- Clinical Committee Staff Support and Coverage Decisions
- Internal Program Operations

HTA Program Proposed Changes

Overall Program

Comments about the overall program and its launch were generally positive. Most commenters indicated that they believed the program is structured appropriately, meeting its basic legislative mandates, and running well. Commenters further reflected that the program is still in its early development stages and the next challenges will be to make adjustments to improve targeted areas and to measure program impact.

Proposed Changes: no major program changes to the five core business functions are proposed. However, improvements within each program function have occurred or are proposed below. Most changes involve clarifying our program processes through timely communication, additional information in easy to use formats, and publishing information in an accessible way.

1. Public Engagement and Transparency

Objective: To ensure transparency and open communication.

Current Program Activities: Hold open public meetings, maintain website communication tool that provides comprehensive program information, respond to stakeholder inquiries and conduct stakeholder outreach.

Proposed Changes:

- The website and stakeholder email list are primary communication tools. The website needs to be updated to reflect that the program is now operational and to better communicate: current events; more information about each selected technology; and the processes that the program uses.
- Program response to stakeholder inquiries has been timely, but also needs to be tracked to ensure adequacy. Internal program mechanisms to support multiple staff access and tracking are now in place.
- Program will continue other stakeholder outreach efforts by attending conferences and association meetings. The program intends to seek the assistance of provider associations to coordinate communication and identify additional stakeholders.

2. State Agency Coordination and Support

Objective: Coordinate and encourage agency participation in the program and support collaboration among state agencies regarding evidence based coverage decisions.

Mechanisms: Weekly meeting with agency medical directors, coordinate agency technology recommendations, coordinate and analyze agency utilization data

Proposed Changes:

- Program needs to provide better support with communication and coordination post-decision. The program will send out an initial communication after key meetings to agency directors, medical directors and executive and legislative staff.
- The program will support development of a template for agencies to use related to decisions and implementation status.

3. Technology Selection and Evidence Review

Objective: Select technologies and provide a systematic review of the evidence by a qualified health technology assessment center.

Mechanisms: Use technology selection process and criteria to select technologies; contract with qualified technology assessment center; review and publish technology assessment reports.

Proposed Changes:

- The program needs to provide a better description of the issues and technology topic so that stakeholders can respond with more targeted information. The program will post more detailed descriptions when seeking public comment.
- Once topics are selected, the program will seek additional ways for public comment where topics are broad or complicates such as holding a teleconference or other meeting for input on key questions.
- The program is scheduled to conduct a technology assessment vendor re-procurement in late fall to assure continued access to top level evidence reviewers.
- The program will develop a report template so that all vendors follow the same basic report format and each report contains information on key sections.

4. Clinical Committee Staff Support and Coverage Decisions

Objective: Provide executive and administrative support to clinical committee and publish coverage decisions.

Mechanisms: arrange and host public meetings; produce minutes and decision; research committee issues; communication link to committee.

Proposed Changes:

- The clinical committee recommended changes to the meeting process that the chair accepted and has already completed to facilitate dialogue on the evidence and coverage decision, and to streamline non-discussion components.
- The program is clarifying its procedures as the communication link with the clinical committee to ensure that the program: is carrying out the committee's intent; is ensuring that communication by stakeholders and agencies is provided to the committee; and is maintaining transparency. A meeting guidance document is being developed.
- The program will recommend to the committee chair that coverage decision and findings document be posted as draft and a 30 day public comment period be held, with a final adoption to be taken at the following public meeting.
- The program has requested an Attorney General review to ensure that the decision process adopted by the committee meets statutory requirements related to consistency with Medicare and Specialty Society Guidelines

5. Internal Program Operations

Objective: Maintain appropriate resources for program activities.

Mechanisms: Management of staff, budget, program metrics.

Proposed Changes:

- The program is participating in agency-level planning exercises to identify program measures and align program with strategic initiatives. Defining measures to be completed by December 2008.
- The program will continue to investigate strategies to reduce redundancy in the production of systematic reviews and other evidence based reports, analysis, and resources.

HTA Program Review

Stakeholder Input Summary

Input gathered through key informant interviews, stakeholder meetings, and planning retreats are summarized below.

HEALTH CARE MANUFACTURERS/INDUSTRY INPUT

1. **Overall/Legal: Insufficient process under APA/ Constitution**
Industry Issue: APA rule writing process has comments for the general issue, proposed decision, and then final decision. Constitutional fairness and due process required given significant liberty and property interest. The HTA process does not meet these standards.
2. **Overall/Legal: Administrative Code are not consistent with the statute**
Industry Issue: the WAC contains language that is not in the regulation. Specifically, there are WAC provisions that set a presumption of non-coverage, and should add CED to WAC list of acceptable decisions.
3. **Technology Selection**
Industry Issue: Medical directors are only interest present when selecting technologies. This is inappropriate because they have a political and budget conflict.
4. **Initial Comments based on technology selected**
Industry Issue: Not enough of a description and off-label uses comments are precluded. The request for information is not sufficiently clear to industry in order to avoid any appearance of marketing off-label use.
5. **Assessment Report**
Industry Issue: Public comments on draft assessment not provided to clinical committee, require that staff presentation include public comments.
6. **Coverage Decision**
Industry Issue 1: Currently no mechanism for public comments to committee until day of decision. Program needs to accept written comments received a week prior to meeting and forward evidence based comments to committee.
Industry Issue 2: Committee is not applying statute; decisions are driven by time constraint not evidence, advisory groups should be convened for complex decisions. Decision criteria not appropriately weight Medicare/treatment guideline questions.
Industry Issue 3: Medical directors sit as a part of the committee's deliberative process and current advisory group is only medical directors who have recognized conflicts of interest.
Industry Issue 4: Public comment on the coverage decision is not permitted until day of decision, and even then public must speculate about what the decision will be based on. Request APA compliance and separate testimony from decision.

LEGISLATOR, LEGISLATIVE and EXECUTIVE STAFF FEEDBACK

- View program implementation and management to date as successful and
- Program operation meets legislative mandates
- Program is providing good balance of diverse interests; high confidence in output
- Executive staff have heard stakeholder concerns over process, would like follow up

- Clinical topics are substantive and tackle high burden disease / difficult technology issues
- Need to measure program impact and cost impact
- Program is proven, needs to provide big results
- Stakeholder feedback to legislators and legislative staff complementary
- Question whether program capacity is sufficient – should be kept in mind as program matures

STATE AGENCY STAKEHOLDERS

HTA Program Overall comments

- Program based on 2006 legislation and Governor health agenda to provide higher quality care and stem cost escalation.
- Program is one component of HCA's mandate to coordinate state agency efforts to develop and implement uniform policies across state purchasing.
- There is a governor expectation that the program produce "big" results.
- US and state trends in medical technology costs are rising, high variation in use demonstrates no clear standard of care, over, under and mis-utilization as high as 1/3 of cost.
- Target paying for effective care based on evidence;
- Program Keys: transparency, evidence review; independent clinical committee; and consistency across state purchasing
- Current agency participation is through agency medical directors in providing consultation to program (technology nominations, data submissions, report reviews, committee meetings).
- Program implementation successful

1. Overall Observations/Issues

- Ensure appropriate engagement with agency directors (business/administration side) not just clinical medical director staff
- Excellent work balancing competing interests; program is providing
- Commission AMDG led Metrics sub-workgroup
- Program should hire Epidemiologist
- AMDG would like Standards
 - *Vendor:* Classifications – for rating / reporting safety / cost / efficacy / quality / classification
 - *Committee:* Translation – translation of evidence to coverage
 - *Committee:* Balance Factors – how to balance efficacy / safety / cost
- For decisions that involve coverage with criteria
 - Recommend triggers for Ad Hoc sub-group
 - Recommend feedback time period prior to final decision
- Program should ensure recognition of committee (e.g. Governor letter)

2. Topic Selection & Prioritization Suggestions

- agency spend / utilization information would be useful
- Investigate use of a method to "scan" for topics/issues
- Involvement of agency directors for business impact and perspective prior to nomination to HCA needed

3. Technology Assessment Vendors and Report Suggestions

- Program should develop and seek guidance on report template

4. Agency Data Suggestions

- Program needs to develop template for report
 - Plain language questions; How much / How many
 - Other common questions; Agency unique data / method
- Agency data will go into report for committee

5. Committee Decisions/Implementation Suggestions

- AMDG needs better program support with communication and coordination
- Program will send out initial communication (one paragraph) that goes to Governor staff to agency directors and AMDG
- Program should support development of template

6. Key Question Suggestions

- AMDG recommends additional staff support (epidemiologist)

PROVIDER and PROVIDER ASSOCIATION FEEDBACK

1. Appreciation for efforts to smoothly launch a complex undertaking.
2. Support for the need for a rational, evidence based process to evaluate technologies.
3. Understanding of the fact that new technologies often bring with them a relative dearth of science based literature regarding their effectiveness and this may lead the HTA in a particular direction when evaluating a technology.
4. A strong urging that the HTA make use of having impartial reviews conducted of both the pros and cons of the technology being reviewed.
5. No issue with the decisions on health benefit and coverage of the five technologies thus far evaluated.
6. Ensuring adequate involvement of professional associations and impacted providers is key; targeting/conducting more outreach to ensure specialty group awareness.
7. Need more local expert involvement
8. Committee should include experts in the clinical area under discussion

Committee Members Feedback

Committee members individually expressed general agreement that the program is progressing well, and individuals are excited to be a part of a new way to address the need for better informed decisions. Both the transparency and evidence review processes were complemented as well as the underlying mandates to make coverage decisions based on evidence. Chair expressed thanks to group for their service, reflected on his role as chair and as a member of this new committee, and his continuing commitment, upon review of the program mandates and bylaws, as well as the progress to date to the program. Committee members agreed that the program and the committee are maturing and that they see a need for only minor revisions to make the process run smoother. Suggestions focused on committee meeting specifics:

1. Meeting Time and Structure Discussion

- Shorten non-discussion items so that discussion can be maximized
- Introduction and housekeeping can be kept to a minimum
- Instruct report vendor to shorten presentation and provide only key discussion and overview of evidence discovered, not book report
- Committee members are expected to come prepared and having read material, no need to rehash, but draw out critical factors – could set the stage for discussion and should be last item prior to discussion
- Cater lunch to help control break spill-over; ½ hour lunch feasible if catered
- Sufficient time for review of one to two technologies; committee continues to mature and with streamlined presentation period
- Committee members should come prepared with top factors/issues to start discussion –chair could collect and decide on top needed to cover

- Chair does excellent job of being inclusive.
- Facilitator may help keep on track in theory but difficulty in segmenting tasks and getting non-biased but informed person.
- Chair should feel free to redirect off topic conversation and no offense is taken.
- Members should challenge each other to tie statements to evidence (this doesn't have to be highest form of evidence, but must have some basis or statement should indicate no evidence and discussion can center on the impact of the lack of evidence for that issue or topic).

2. Public Comments / Testimony

- Many comments have not focused on evidence; individuals not familiar or informed about legislative mandate;
- Public comments are important and may provide additional insight or perspective on evidence
- Time needs to be managed and kept to set overall period – current may be too long, but depends on topic
- Current staff management of scheduled and day of testimony fine

3. Process for decision; decision tool; voting

- The amount of questions for voting, and sub questions for each one (yes, no, inclusive, confident, not confident) is very tedious
- Elimination of confident or not confident vote in tool would be helpful
- Process of listing the available evidence that exists for safety, efficacy, and cost-effectiveness will enhance transparency and increase relationship between evidence committee considers best to rely on and decision
- Identifying evidence should make voting process and tool more streamlined, tool and or voting questions could be phrased more like: “Is there sufficient evidence in some or all circumstances?”
- Identification of key factors up front will facilitate outcome and better identify key discussion items
- Staff should develop cards or investigate feasibility of an electronic voting system for the vote variables (e.g. “cover”, “not cover”, or “conditional cover”)

4. Discussion trigger for conditional cover

- Update tool or have staff develop a recommendation on a process for triggering further discussion on conditional coverage
- Separate decision on yes/no/sometimes from the identification of the situations if the decision is sometimes
- The sometimes decisions/discussion is where there may need to be additional process, more information, etc, so having a trigger here is good. Chair and committee may want input from administrator or ad hoc group if technical question at issue, or simply a process to solicit information or feedback
- Time spent on crafting language/word-smithing detracts from substantive discussion. One approach would be to vote on evidence and overall question, then direct staff to prepare a decision document for final adoption at next meeting.

OTHER FEEDBACK

- Recognition of pioneering practice - commitment to transparency and using evidence on safety, efficacy and cost
- Appreciation of magnitude of effort and change in health industry attitude to accept the process and that timely decisions have been produced
- Maturity of the clinical committee in capability of focusing on meaningful information; level of familiarity with evidence concepts, and ability to move beyond technical performance discussion to benefit, important health outcomes, and cost effectiveness.

ATTACHMENT A

HTA Program Review – Discussion Document

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Purpose of Discussion

The Health Technology Assessment program has completed its first full year of operation. The program values communication with legislators, legislative staff, the governor's policy and fiscal staff, other state agencies, and public/private stakeholders. We appreciate your assistance in providing the program with feedback on the program's operation and outcomes.

Discussion Questions

1. Has HTA met the legislative mandate to:
 - Use objective and valid scientific evidence to make coverage decision?
 - Make state agency coverage decisions more consistent?
 - Make coverage decisions more transparent?
2. In achieving these mandates, which aspects should HTA:
 - Focus more attention?
 - Focus less attention?
 - Maintain current focus?
3. What can HTA do to provide better service to you?

Health Technology Assessment Program

	Health Technologies			Evidence			Decision	
	Topic	Report	Date	Safe	Effective	Cost	Health Benefit	Coverage
1	Upright MRI	✓	May-07	Equal	Insufficient	More	N/A	No
2	Pediatric Bariatric Surgery - Under 18	✓	Aug-07	Insufficient	More	Insufficient	No	No
	Pediatric Bariatric Surgery - 18-21 yr	✓		Less	More	Insufficient	Yes	Yes/ Conditions
3	Lumbar Fusion	✓	Nov-07	Less	Equal/More	More	Yes	Yes/ Conditions
4	Discography	✓	Feb-08	Insufficient	Insufficient	Insufficient	No	No
5	Virtual Colonoscopy (CTC)	✓	Feb-08	Equal	Equal	More	No	No
6	Intrathecal Pumps (for chronic non-cancer pain)		Aug-08					
7	Arthroscopic Surgery of the Knee		Aug-08					
8	Artificial Discs		Aug-08					
9	Computed Tomographic Angiography (CTA for cardiac care)		Aug-08					
10	Cardiac Stent (off label usage)		Nov-08					