

HTCC Ad Hoc Advisory Group Cardiac Stent – Conditions of coverage

Objective: Advisory groups provide a report and/or testimony to the committee on the key questions identified by the committee as requiring the input.

Membership: The HTCC chair convenes the group and is an ex officio member. Group should include at least 3 members, including an enrollee, and two experts - one an advocate and one a critic of the technology. Members must abide by conditions set by administrator and a majority should not have financial stake in outcome.

Committee Discussion - Majority of committee members concluded that:

- The record is clear that there is strong evidence from multiple RCTs that mortality and acute MI rates are not different between DES and BMS
- There is a benefit to DES in that target vessel revascularization/target lesion revascularization rates are lower by 11%
- This benefit was not large enough to outweigh the significant cost for all populations, but groups at high risk of restenosis may benefit the most.
- Groups at high risk of restenosis are not definitively established. The committee adopted the broadest definition, among other entities that had established restrictions.

The HTCC has made a preliminary decision to cover drug eluting stents under certain conditions. The conditions are: Cover for patients at high risk of restenosis, including patients with: diabetes, vessels smaller than 3 mm, or lesions longer than 15 mm.

HTCC Decision to request Advisory Group: Based on public input and committee discussion, the committee would like additional expert input prior to finalizing the conditional coverage criteria to ensure that additional high risk groups were not inadvertently left out.

Ad Hoc Advisory Group Scope and Role: Participate in a group of technical experts to identify groups at high risk of restenosis and the evidence supporting it that are not currently included in the draft criteria. Approve a report to the HTCC, in time for distribution prior to the October 30, 2009 scheduled meeting. Subject to discussion within the group, provide testimony to the HTCC at the October 2009 meeting.

Work Product:

Specialized expertise to advise on:

- groups not currently included that are at high risk of restenosis
- evidence supporting group as high risk

Work Schedule:

Meeting 1:	October 5 th , 2009 from 1 to 5 PM	- 4 hours
Meeting 2:	October 16 th , 2009 from 1 to 4 PM	- 3 hours
Final Report Due:	October 23, 2009	(one week prior to meeting)
Testimony, if needed:	October 30, 2009	

Ad Hoc Advisory Group Members:

Brian Budenholzer, HTCC Chair
Richard Phillips, HTCC Member
Spectrum Research, Evidence Vendor

Dr. Michael Ring

Dr. Steven Goldberg

Dr. Rita Redberg

Potential: Hospital Association Representative, Payer representative

First Meeting Materials

- Agenda
- Review Ad hoc Group assignment and work plan
- Conflict Disclosure (Completed and previously submitted)
- Initial List of high risk groups and any evidence supporting for discussion (Completed and previously submitted Staff to combine)

Second Meeting Materials

- Agenda
- List of Groups at high risk of restenosis; evidence; and discussion incorporated from meeting 1

Final Report

- Final List of Groups at high risk or restenosis
 - Will include cited evidence, primary discussion points
 - May include recommendations

Initial List of Groups at high risk for restenosis

Staff has reviewed public comment on original cardiac stent criteria and summarized additional categories (may or may not have been referred to as “high risk”) that were advocated for inclusion. Ad hoc advisory members providing expert input need to review the list and state: (a) is this group already included, b) do you believe this group is at high risk of restenosis, (c) strongest evidence supporting that the group is at high risk of restenosis, and (d) identify other groups not already captured and strongest evidence supporting. Staff will combine responses into an initial list with evidence citations for first meeting.

FDA Label – DES advocated

Potential High Risk Group	Already Included (Y/N)?	High risk of restenosis (Y/N)?	Strongest Evidence supporting (# and cite at end)
Diameter should be 3mm or less, not less than 3mm			
Other: _____			

Off label indications where DES advocated

Potential High Risk Group	Already Included (Y/N)?	High risk of restenosis (Y/N)?	Strongest Evidence supporting (# and cite at end)
Target vessel revascularization for in-stent restenosis			
(Unprotected) Left main coronary			
Bifurcation lesion			
Bailout stenting			
Chronic Total Occlusion			
Saphenous vein graft			
Ostial lesions			
Bypass graft related to prior CABG			
Acute MI/Emergent <ul style="list-style-type: none"> o STEMI, NSTEMI, Unstable angina 			
Other:			

Committee or Workgroup Conflict of Interest Guideline

Introduction

The HTCC Workgroup is a public service workgroup established to safeguard the public interest by identifying medical tests and treatments where evidence shows they are safe, effective, and cost-effective. Balance, independence, objectivity and scientific rigor are a basis for public trust and crucial to the credibility and integrity of decisions.

Guiding Principle

Conflict of Interest decisions must be disclosed and balanced to ensure the integrity of decisions while acknowledging the reality that interests, and sometimes even conflicting interests, do exist. Individuals that stand to gain or lose financially or professionally, or have a strong intellectual bias need to disclose such conflicts.

For example, the fact that a member or stakeholder is a health care provider that may use a service under review creates a potential conflict. However, clinical and practical knowledge about a service is also useful, and may be needed in the decision making.

Procedure

Declaration of real or potential conflicts of interest, professional, intellectual, or financial is required prior to membership or provision of written or verbal commentary. Participants must sign a conflict of interest form; stakeholders providing comment must disclose conflicts.

The HTCC Chair or HCA Administrator shall make a decision, in his/her sole discretion, as to whether a conflict of interest rises to the level that participation by the conflicted participant could result in a loss of public trust or would significantly damage the integrity of the decision.

HCA defines conflict of interest as any situation in which a voting member or anyone who provides written or verbal testimony regarding products, services, or technologies discussed or voted on during the workgroup meeting, has a relationship with a manufacturer of any commercial products and / or provider of services discussed or voted on during the meeting. Relationship extends to include immediate family member(s) and / or any entity in which the member or person testifying may have an interest.

A relationship is considered as:

1. Receipt or potential receipt of anything of monetary value, including but not limited to, salary or other payments for services such as consulting fees or honoraria in excess of \$10,000.
2. Equity interests such as stocks, stock options or other ownership interests in excess of \$10,000 or 5% ownership, excluding mutual funds and blinded trusts.
3. Status of position as an officer, board member, trustee, owner or employee of a company or organization representing a company, association or interest group.
4. Loan or debt interest; or intellectual property rights such as patents, copyrights and royalties from such rights.
5. Manufacturer or industry support of research in which you are participating.
6. Any other relationship that could reasonably be considered a financial, intellectual, or professional conflict of interest.
7. Representation: if representing a person or organization, include the organization's name, purpose, and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).

HTA Workgroup or Participant Disclosure

Any unmarked topic will be considered a "Yes"

	Potential Conflict Type	Yes	No
1.	Salary or payments such as consulting fees or honoraria in excess of \$10,000		
2.	Equity interests such as stocks, stock options or other ownership interests		
3.	Status of position as an officer, board member, trustee, owner		
4.	Loan or intellectual property rights		
5.	Research funding		
6.	Any other relationship		

If yes, list name of organizations that relationship(s) are with and for #6, describe other relationship:

	Potential Conflict Type	Yes	No
7.	Representation: if representing a person or organization, include the name and funding sources (e.g. member dues, governmental/taxes, commercial products or services, grants from industry or government).		

7. If yes, Provide Name and Funding Sources: _____

If you believe that you do not have a conflict but are concerned that it may appear that you do, you may **attach additional sheets** explaining why you believe that you should not be excluded.

I certify that I have read and understand this Conflict of Interest Form and that the information I have provided is true, complete, and correct as of this date.

X

Signature *Date* *Print Name*

FOR QUESTIONS: Denise Santoyo, Health Care Authority, 360-923-2742, PO Box 42712, Olympia, WA 98504-2712

APPENDIX A

RCW 70.14.080 - Definitions:

The definitions in this section apply throughout RCW 70.14.090 through 70.14.130 unless the context clearly requires otherwise.

(2) "Advisory group" means a group established under RCW 70.14.110(2)(c).

RCW 70.14.090 - Health technology clinical committee:

(3) Meetings of the committee and any advisory group are subject to chapter 42.30 RCW, the open public meetings act, including RCW 42.30.110(1)(l), which authorizes an executive session during a regular or special meeting to consider proprietary or confidential non-published information.

(4) Neither the committee nor any advisory group is an agency for purposes of chapter 34.05 RCW.

(5) The health care authority shall provide administrative support to the committee and any advisory group, and may adopt rules governing their operation.

RCW 70.14.110 - Health technology clinical committee determinations:

(2) In making a determination under subsection (1) of this section, the committee:

(a) Shall consider, in an open and transparent process, evidence regarding the safety, efficacy, and cost-effectiveness of the technology as set forth in the systematic assessment conducted under RCW [70.14.100](#)(4);

(b) Shall provide an opportunity for public comment; and

(c) May establish ad hoc temporary advisory groups if specialized expertise is needed to review a particular health technology or group of health technologies, or to seek input from enrollees or clients of state purchased health care programs. Advisory group members are immune from civil liability for any official act performed in good faith as a member of the group. As a condition of appointment, each person shall agree to the terms and conditions imposed by the administrator regarding conflicts of interest.

182-55-045 Advisory group.

(1) The committee chair, upon an affirmative vote of the committee members, may establish ad hoc temporary advisory group(s) if specialized expertise or input from enrollees or clients is needed to review a particular health technology or group of health technologies. The purpose or scope of the advisory group and time period shall be stated. The advisory group shall provide a report and/or testimony to the committee on the key questions identified by the committee as requiring the input of the advisory group.

(2) Advisory group membership: An ad hoc temporary advisory group shall include at least three members. Membership should reflect the diverse perspectives and/or technical expertise that drive the need for the specialized advisory group. The advisory group will generally include at least one enrollee, client, or patient; and two or more experts or specialists within the field relevant to the health technology, preferably with demonstrated experience in the use, evaluation, or research of the health technology. If substantial controversy over the health technology is present, at least one expert that is a proponent or advocate of the health technology and at least one expert that is an opponent or critic of the health technology should be appointed. A majority of each advisory group shall have no substantial financial interest in the health technology under review.

(3) As a continuing condition of appointment, advisory group members:

(a) Must complete an advisory group member agreement, including a conflict of interest disclosure form, and keep disclosure statements current;

(b) Must abide by confidentiality requirements and keep all personal medical information and proprietary information confidential; and

(c) Shall not utilize information gained as a result of advisory group membership outside of advisory group responsibilities, unless such information is publicly available.

3.4 Officers: Chair and Vice-Chair

..... Duties of the Chair include ratifying the bylaws and any amendments; presiding over meetings of the Committee; assisting with development of Committee agenda, programs, and other materials; reporting to the Administrator on Committee activities and decisions; appointing ad hoc temporary advisory groups and serving as ex-officio member of all advisory groups.

3.5 Advisory Groups

The Chair may establish temporary ad hoc advisory groups if specialized expertise is needed to review a particular health technology or group of health technologies, or to seek input from enrollees of clients of state purchased health care programs. Advisory groups must have a defined objective related to a health technology or group of health technologies and must report back to the Chair and Committee. Advisory groups are subject to, and shall be convened according to, RCW§70.14.100 and WAC§188-55-045.