HTCC Ad Hoc Advisory Group
Technical Input on:
Cardiac Stent Conditions of coverage

1. Overview of Workgroup background, purpose, and membership.

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.

- Brian Budenholzer, HTCC Chair
- Richard Phillips, HTCC Member
- Andrea Skelly, Spectrum Research, Evidence Vendor
- Jeff Thompson, Medicaid Medical Officer
- Dr. Gordon Kritzer, Cardiologist and Hospital Association Representative
- Dr. Michael Ring, Cardiologist Subject expert
- Dr. Steven Goldberg, Cardiologist Subject expert
- Dr. Rita Redberg, Cardiologist Subject expert

Background: 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.

Committee Discussion - Majority of committee members concluded that:

- The record is clear that evidence from multiple RCTs and registry studies 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 reduced by an average of 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 from DES.
- Groups at high risk of restenosis are not definitively established. The committee adopted the broadest definition, among other entities that had established restrictions.

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 report or testimony to the HTCC.

2. Workgroup results

The workgroup met twice - on October 5th and 16th and selected Dr. Mike Ring to serve as the clinical chair. The workgroup started with a review of the task and a discussion of the potential high risk categories that were included in public comment. The list was updated based on comments, and members submitted some articles and other information to a central repository; reviewed the information; and eventually provided a ranking from 0 to 10 of importance of certain risk categories.

The ranking criteria were not precisely defined and were designed to get a basic sense of how workgroup members judged the risk categories in a survey. Upon discussion of the 0 to 10 ranking at the second meeting, the focus is on the individual's judgment combining evidence that they find relevant and their clinical judgment of these potential categories as high risk at incidence of restenosis or when occurs the patient at higher risk of a poorer outcome. General rule of thumb regarding ranking:

- 10 is a definite/absolute, condition or issue fits and data so strong
- 8 being a score that it should definitely be covered
- 3 being a score that shouldn't be covered
- 0 should not be even considered or no or limited evidence

Potenial High Risk Groups	*Budenholzer*	*Phillips*	*Goldberg*	*Ring*	*Redberg*	*Kritzer*	*Thompson*	*Skelly*	*ALL AVG*	*AVG Card.*
TVR for in-stent restenosis	**5**	**8**	**10**	**9**	**3**	**9**	**0**	**0**	**5.50**	**7.75**
Pro/Con Comments	• Studies submitted did not compare BMS vs. DES; focused on BMS failure but not DES failure; • Data are limited but a meta-analysis of four RCT showed DES better than either PTCA or brachytherapy					• Newer studies wouldn't compare BMS to DES in higher risk because wide recognition that BMS has limitations. Study in early 2000s showed repeat stenting with BMS no more effective than PTCA alone and brachytherapy decreased restenosis Early studies show that radiation is less effective than DES, so DES better than brachytherapy as comparator. • Greater than 1 in 10 benefited in difficult population; expect increase in restenosis with more use of BMS, so need to include				
Left main coronary	**7**	**9**	**10**	**9**	**3**	**10**	**0**	**0**	**6.00**	**8.00**
Pro/Con Comments	• most studies did not compare DES vs. BMS; Only one study -Erglis RCT in 203pts; 2%vs16%; TVR rate; 14% RD, NNT of 7 • In contrast to most forms of restenosis, restenosis of the left main is known to be a high risk condition and is associated with					• Largest Left main study (360pt) – SYNTAX bypass surgery to DES and in study equivalent w/ outcomes of Death/MI 10% to 1.5% in favor of DES over CABG. Further RCT between PCI and CABG likely are needed to recommend PCI for left main				

Potenial High Risk Groups	Budenholzer	Phillips	Goldberg	Ring	Redberg	Kritzer	Thompson	Skelly	ALL AVG	AVG Card.
	sudden cardiac death. • Considerable discussion about the appropriateness of stenting the left main but it is current practice to in patients who are either non-surgical candidates or very high risk for CABG					revascularization in patients who are also candidates for CABG				
Bifurcation lesion	**5**	**5**	**8**	**7**	**2**	**8**	unknown	**0**	**5.00**	**6.25**
Pro/Con Comments	• Subanalysis of SCANSTENT RCT- 6% vs 21% TVR rate (126 pts); subanalysis does not preserve randomization; other studies did not compare DES vs. BMS; • Columbo - showed 25% revascularization overall -is this effective strategy? • literature suggests small vessels covered by other criteria; evidence did not weight heavily to include					• These are difficult pts at high risk of revascularization; angiographic rates will be higher esp. in side branch; side-branch stenting is usually done on a provisional basis if PTCA alone inadequate • side branch vs. main branch may differ in size				
Chronic Total Occlusion	**8**	**6**	**9**	**8**	**2**	**8**	JACC 1-8	**5**	**6.57**	**6.75**
Pro/Con Comments	• Keep criteria simple, already covered 90 to 95% of time;					• 1 RCT; 2 cohort studies - about 29% risk differential. Prison II; TVR 7%vs 27%; 4% vs. 23%; 5% and 31% differences. • Lot of effort to open up pt; very high risk of restenosis				
Saphenous vein graft	**3**	**3**	**6**	**1**	**2**	**6**	unknown	**0**	**3.00**	**3.75**
Pro/Con Comments	• 2 small RCT (SOS and RRISC) SOS shows risk difference at 23% and 16%; RRISC shows risk difference 6% vs 5% so conflicting results; may be underpowered					• Data are clearly limited, but vein grafts tend to be larger vessels; - SVGs often have progression of disease diffusely already had bypass surgery; should not deny DES therapy - in patient population at higher risk for repeat CABG				
Ostial lesions	**3**	**5**	**9**	**5**	**2**	**8**	unknown	**0**	**4.57**	**6.00**
Pro/Con Comments	• tend to be higher restenosis areas; not much data; likely included in current criteria and other risk groups					•				
STEMI	**3**	**7**	**8**	**5**	**2**	**6**	non-emerg	**0**	**4.43**	**5.25**

Potenial High Risk Groups	*Budenholzer*	*Phillips*	*Goldberg*	*Ring*	*Redberg*	*Kritzer*	*Thompson*	*Skelly*	*ALL AVG*	*AVG Card.*
Pro/Con Comments	• 5 meta-analysis (Braer largest recent - 13 trials); result/ risk is not different than general population; 5.3% DES vs 11.2% BMS with risk difference of 6.2% NNT 16 - large overlap in RCTs used among meta-analyses; • Often emergent and don't know pt well enough to gauge likely compliance with dual anti-platelet therapy • Per COAP data, current practice in WA state is to use DES less than 50% of STEMI patients					• One of the highest risk pts; not necessarily failure of technology; some staged treatment; both safe; impact on TVR modest; • Experience is that DES pts consistently come back less				
>15 mm of total stent placed w/i vessel	**9**	**8**	**10**	**9**	**6**	**8**	unknown	**1**	**7.29**	**8.25**
Pro/Con Comments						• Risk clearly related to length of stent - may have areas where need to use two shorter stents totaling over 15mm in same vessel; • more stents placed, more risk of restenosis so at higher risk • Using multiple DES in same vessel does not cost the State more but more likely to decrease chance of further revascularization procedures				

Workgroup Recommendation regarding base Criteria

Current criteria for less than 3mm vessel

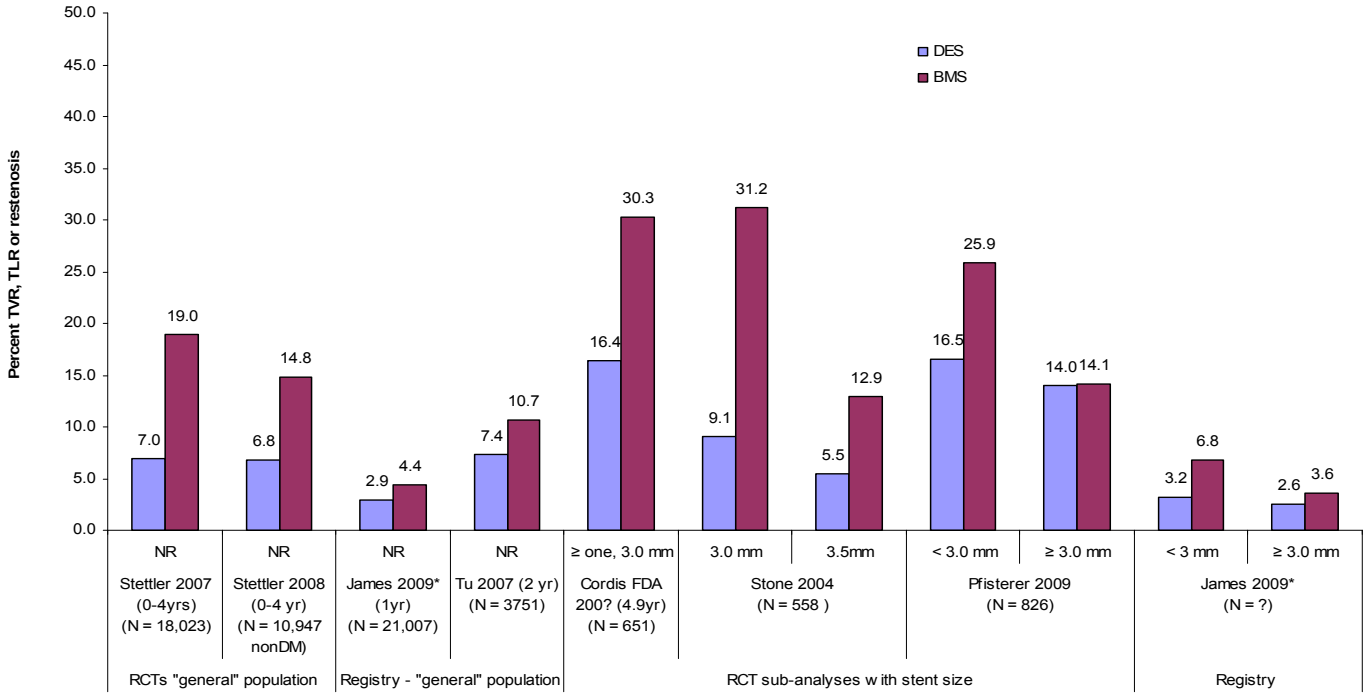
- Two issues – the size and gauging by vessel or stent
- Routine clinical practice to insert a larger stent than the reference vessel.
  - If you use vessel size, then difficult to operationalize because not generally recorded, interventionalists use different measures; may become gaming in that vessel size; too much variability and subjectivity
  - If you use stent size, then easier to operationalize and "measure"; but generally oversize the stent so could result in tightened criteria

Evidence availability on size: registry data do not show difference; and not different from overall risk basis; RCTs have mixed results – see figure below

- Stone 3mm stent; 3.5mm stent
- Fisher looked at 3mm vs. less than 3 mm
- James study: less than 3mm; and greater than 3mm

Recommendation: committee change criteria to – Equal or less than 3.0mm stent

Figure: Comparison of TLR, TVR or restenosis rates for "general" populations and with respect to stent diameter



* James data for restenosis at 1 year among those with 1 stent

Context and comments on the current draft HTCC criteria relative to the potential categories

- Where would current criteria on vessel length and size not apply to potential added high risk categories:
- these high risk categories could all be included; but some may not fit size
- Concern if already included, criteria is sound that committee came up with, too many exceptions and you won't have rule
- Of the groups looked at, how many additional patients added to current criteria – likely 1 to 2% per item; with total close to 20% and half already in
- Practically may not be much more, but recognition that cardiologists have additional or different criteria than
- From experience/COAP, likely about 25% to 30% are diabetic; about 2/3 not

Additional issues, and concerns

There were additional issue that were raised by a subworkgroup participant, though these issues are not necessarily shared and in some cases disputed by other participants. The issues and concerns are around the clinical committee's draft decision, but cover larger policy, operational, clinical and methodolgic topics that are relevant to the decision and may influence the discussion, but were not within the direct scope of the workgroup.

- Hospital issue of coverage in emergent situations – operationally infeasible

- Large state reimbursement differential between bare metal and drug eluting not reflective of acquisition costs, and if difference was a lot less, wouldn't be meeting
- Other requirements or parameters before certain PCI's (e.g. elective left main) and poor surgical candidate
- Concern that this process uses some evidence, though not systematically searched and the evidence is outside of that included in the technology assessment due to relevance, so technology assessment is being "extended" in new direction without benefit of systematic review which may turn up additional relevant documents
- Overall issue of appropriateness of PCI versus another intervention impacts comparators as well as policy and views on meaningful difference
- Two different views of clinically meaningful difference between BMS and DES:
    - Lower rates of restenosis are not indicative of better clinical outcomes because target vessel revascularization does not reduce symptoms (pain not well correlated with restenosis rates) nor reduce rates of death or MI
    - Clear evidence on limitation of BMS, restenosis rates are higher and committee recognized that for high risk groups, this is a benefit; TVR is not benign; not all studies used angiographic only and current practice for restenosis are symptom (pain) driven and rates are lower for DES; the groups considered are at high risk for revascularization or are high risk for complications or more severe complications
- Use of DES stents "off-label" in more complex coronary lesions is associated with higher risk of stent thrombosis, MI or death according to NICE appraisal
    - Cumulative data for death and MI are reported under efficacy (RCTs/ Meta-analyses) and under effectiveness (non-randomized/registry studies) and where available, analysis by dual anti-platelet therapy provided. A higher mortality risk is noted for diabetic patients who had less than 6 months of dual anti-platelet therapy, but not among those with 6 or more months. Data again are not separated out by on label vs. off label use. Assessment also included FDA panel statements and issues regarding primarily stent thrombosis.

APPENDIX A: Data abstract to subgroup

Spectrum provided a summary of TLR/TVR rates in general and for various conditions listed for sub committee consideration are presented below, based on articles in HTA and very cursory abstraction from additional aticles suggested by ad hoc committee,

Articles (aside from those in the HTA) did not undergo critical appraisal and suggested articles are not based on systematic search or review of literature.

From an evidence-based perspective, there are a number of concerns that should be raised with regard to ranking the conditions listed, the process for determining risk and extent to which DES may provided added value (clinical and economic) over BMS.

A. The process does not provide a systematic approach to identifying or evaluating the evidence, leading to potential bias in evaluation as alluded to by Dr. Ring on our first call.
    1. While there is benefit to expert opinion, it is generally perceived to be the lowest level of evidence. There is the danger that, regardless of disclaimers to the contrary, any report will be construed as being "evidence-based".
    2. Articles submitted for consideration (beyond those already in the HTA) may not represent all relevant articles that would be appropriate to consider since no systematic literature search based on criteria established up front has been done. A number of articles have been published since the time that the HTA search was done (January/February 2009).
    3. There are no *a priori* criteria for inclusion/exclusion of citations.
    4. Evaluation of isolated articles without consideration of aggregate data (e.g. from summaries of relevant articles, pooled data or meta-analyses) is potential misleading..
B. Study quality needs to be considered. There is potential for bias in non-randomized studies even with adjustment. There are mixed results from such studies for various outcomes reported in the HTA
C. There should be consideration of broader clinical outcomes over time such as death and MI.

"General" or "Background" risk of TLR or TVR

Author	Design	Population	DES	BMS	Effect size
Meta-analyses /RCTs					
Stettler 2007	Meta analysis, 38 RCTs (network) N = 18,023	Broad Population (0-4 yr)	6% -9%	19%	RD = 10-13% NNT = 8 to 10

Stettler 2008	Meta analysis, 35 RCTs (network) N = 10947 non DM N = 3852 DM	Non DM Population (0-4 yrs) (≥ 6 mos dual anti-platelet) DM (0-4 yr) (≥ 6 mos dual anti-platelet)	5.6%-7.8% overall 6.8% 9.7%	 14.8% 22%	 RD = 8% NNT = 13 RD = 12.3%
Kirtane 2009 (pub after HTA)	Meta-analysis of 22 RCTS, N = 9470 (including 8 off label trials)	TVR – 16 – RCTs vs. BMS	NR	NR	
Non-Randomized/Registry Studies					
Kirtane 2009	Meta-analyses of non-randomized studies 34 studies N = 182,901	TVR – 18 observational studies	NR	NR	
Various authors (summaries from SRI HTA)	REGISTRY AND NON RANDOMIZED studies	General	5.2% - 14.2%	8.1% - 24.4%	RD low ranges 2.9% RD High ranges 10.2%
Douglas 2009* (included for context)	ACC-NCDR Registry study	Medicare population (revascularization from ICD-9 to 30 mos)	23.0%	24.5%	RD = 1.5% NS after adjustment
James (2009)* (From HTCC presentation)	SCAAR registry study	Restenosis- at 1 year, 1 stent group (DES n = 12,358, BMS n = 8649) Overall	 2.9%	 4.4%	 RD = 1.5%
Tu (2007) Ontario (and in HTA)	Population based registry study N = 3751	after adjustment) 6 mos TVR 1 year TVR 2 year TVR	 3.2% 5.2% 7.4%	 6.0% 8.6% 10.7%	RD 2.8% 3.4% 3.3%

STEMI

- **Menichelli (SESAMI) (2007) and Spaulding (Typhoon)** included in all meta-analyses; not listed separately
- **Kelbaek (2008) (DEDICATION)** are in DeLuca and Brar meta-analyses
- **Guagliumi (2009) CADILLAC) –** Not comparison of DES vs. BMS

	Author	Design	Population	DES	BMS	Effect size
H - I	**Meta-analyses in Acute MI (STEMI)**					

	Brar* 2009 (From HTCC presentation)	Meta-analysis (13 RCTs) N = 7352	Acute MI - STEMI TVR (2 years)	5.3%	11.5%	RD = 6.2% NNT = 16 NS diffs in death or MI
	De Luca 2009	Meta-analysis 11 RCTs, N = 3605	STEMI 12 month TVR 18-24 month (4 RCTs)	3.4% 5.5%	12.6% 13.5%`	RD = 9.2% RD = 8.0 %
	Pasceri 2007	Meta-analysis 7 RCTs N = 2786	Acute MI	4.8%	12.0%	RD = 7.2% NNT = 14
	Kastrati 2007	Meta-analysis 8 RCTs N = 2357	Acute MI (reintervention)	5.1%	13.1%	RD = 8% NNT = 12.5
	De Luca 2009 J Thromb, Thombolysis	Met-analysis 9 RCTS N = 2769	STEMI 12 TVR (9 trials) long term (4 trials)	4.5% 8.1%	12.7% 19.6%	RD 8.7% RD 11.5%, NNT = 9
Next highest level (RCT)	**New RCTs – Acute MI**					
	Stone 2009 NEJM	RCT N = 3006 Randomized	STEMI " ischemia driven" TLR at 12 mos TLR	4.5%	7.5%	RD = 3% NNT = 33 NS diff i**n MI or Death**
	DiLorenzo (2009) PASEO **IN Kastrati, Brar and DeLuca Meta-analyses**	RCT Single center N = 270 randomized)	Consecutive STEMI pts TLR	SES 5.6% PES 6.7% ANY 6.1%	21.1%	RD = 15% **NS diffs in death or MI**
	Diaz De L Llera (2007) **IN Brar and DeLuca Meta-analyses**	RCT N = 120	STEMI 12 month TVR	0% (does not include 1 urgent TVR by 30 days)	5.7% does not include 1 urgent TVR by 30 days)	RD 5.7% (NS diff) NNT = 17.5 **NS diffs in death, MI**
	OTHER REPORTS					
low level of evidence (comparative, nonrandomized	**Various authors** (summaries from SRI HTA)	Registry/non-randomized studies - summary of ranges	Acute MI, ULMCA (TLR or TVR, >1 yr) [1-5]	3.4%-8.0%	5.1% -15.2%	
	Columbo (2007)	Review article, not systematic review or meta	RE: STEMI Includes RCTS already in Metas with non randomized studies Unclear from tables if TLR% is for DES only –Ranges are	NR	NR	

			from 1.1% - 6.2% Ranges for restenosis are from 5.9%- 9.3%			

In-stent re-stenosis (ISR)

The original HTA was to evaluate the question of whether DES confer incremental benefit over BMS. The citations provided do not appear to be relevant to the question but appear more relevant to a broader question which seems beyond the scope of the ad hoc committee, namely does DES work better than brachytherapy or other treatment for in-stent re-stenosis. Seems like a similar dilemma of comparing DES (or any stent) to CABG. These seem to be beyond the scope of the HTA and the ad hoc committee. Studies selectively studied those with failed BMS it seems……what about those with failed DES? It is assumed the failed DES would also require revascularization

Dibra (2006) – this is a meta-analysis of studies comparing treatments for in-stent restenosis among patients who had BMS-related in-stent re-stenosis. It does not give rates of re-stenosis with DES nor does it describe DES vs. BMS for the treatment of in-stent restenosis. The committee's question is not whether to cover DES vs. other treatment (e.g. brachytherapy) for in-stent restenosis. Other unanswered questions:

- Is in-stent re-stenosis a bigger problem with BMS vs. DES? How much bigger? (i.e. what is the rate of in-stent restenosis in DES vs. BMS?)
- Among those who had DES with in-stent restenosis, does putting another DES in improve outcomes vs. putting BMS. In other words, what are the data/rates? Do these studies ignore the idea that in-stent restenosis also occurs (even if less often) in DES placed de novo?

Sheiban (2009) – Post DES restenosis in ULM

- Post-DES restenosis in 70/718 (9.7%) pts with ULMCAD; 48.6% had additional DES for tx, 10% CABG – only overall TLR reported (n = 15, 21.4%); MACE for DES 25.4%

Others

- **Alfonso 2006** – RCT of balloon angioplasty vs. SES to treat ISR
- **Holmes (2006)** – RCT SES vs. Brachytherapy to treat ISR within a BMS
- **Liistro (2006)** – 2 center registry, case series; SES only? N = 244 with indications for repeat intervention; TLR 4.9%
- **Ellis (2008)** PES vs. vascular brachytherapy to treat ISR within a BMS; TLR at 24 months w/PES 10.3%; TVR 18.1%
- **Stone 2006** – RCT of PES vs. Brachytherapy to treat ISR within a BMS
- **Chen 2006 –** describes presentation of BMS- related IRS as acute MI, UA; d

Unprotected Left Main

- **Mehilli –** PES vs. DES; not within scope
- **Montalescot G (2009),** not comparison of DES vs BMS – Global Registry of Acute Coronary Events (GRACE) N = 1799; PCI(in general) vs. CAGB vs. Neither

	Author	Design	Population	DES	BMS	Effect size
Highest	**NONE**					
Next level RCTS	**NONE**					
low level of evidence –non randomized studies	**Biondi-Zoccaci 2008** includes Chieffo (2005 and 2006) Palmerini they excluded Erglis	Meta-analysis of 3 registry/ nonrandomized studies N = 396	ULMCA	% NR (report overall rate of 6.5% for DES based on all studies including noncomparative)	%NR	RD ? OR = 0.34 (95% CI, 9,12-0.94)
	Buzman (2009)	Resgistry study N = 252	ULMCA 60.3% had NSTE-ACS 44.8% previous MI 31.3% previous PCI	% NR	% NR	Only overall rate of TLR reported = 8.3% ; TLR by stent type NR
	Palmerini (2008)	nonrandomized N = 1111 DES and 342 BMS	ULMCA, ACS in 55% % DES and 70% BMS	% NR	% NR	Data not provided
	Columbo (2007)	Review article, not systematic review or meta	RE: ULMCA Unclear from tables if TLR% is for DES only – Ranges are from 2%-38 % based on 5 studies, N = 489 Ranges for restenosis are from 7%- 38%	% NR	% NR	Data not provided
lowest level (case series	**Chieffo (2007)**	CASE SERIES consecutive pts N = 147	ULMCA (tx of bifurcation not required) IVUS as adjunct 52% ostial, 28 % shaft	TLR in hosp, during f/u 0.7 % (n = 1) for both TVR in hosp 0.7 % (n = 1); at last f/u 4.7% (n = 7)	NR	RD - incaclulable

Bifurcations

Most of the studies do not compare DES vs. BMS and therefore not possible to evaluate incremental benefit of DES; The TLR for these studies seems high. Just looking at the numbers raises a question: Is a technology that fails ¼ of the time something that should be considered an effective strategy?

Columbo (2004) – does not provide data comparing DES and BMS to

- Compares stenting of main and side branches with DES (double stent) vs. DES in main and PTCA for side (single stenting); not comparative of DES vs. BMS
- Rates of restenosis at 6 months were 25.7% total, 28% double stenting and 18.7% single stenting with NS diff between groups

Columbo (2009)

- RCT of different stenting techniques

	Author	Design	Population	DES	BMS	Effect size
Highest	**NONE**					
Next level	**NONE**					
low level of evidence	**Thuesen (2006) (Appendix)**	Sub-analysis of SCANSTENT† (prospective cohort) N = 126	Bifurcated (TVR)	6%	21.1%	RD 15.1% NNT = 7
	Columbo (2007)	Review article, not systematic review or meta	RE: Bifurcation Lesions Not comparisons with BMS TLR% is for DES only for main vs. side + main stenting; based on 3 RCTs, 3 nonrandomized Ranges for restenosis are from 11.3% - 25.7% and TLR 2.0 % - 11.3%	% NR	NOT PART OF STUDY	Data not provided

Chronic Total Occlusions

- Rahel (2008) PRISON II – included in Stettler and Kastrati and other meta-analyses
- Suttorp 2006 and Rahel (2008) – report on same trial

	Author	Design	Population	DES	BMS	Effect size
Highest	Meta-analyses					
	NONE					
Ne						

	Rahel (2009)	RCT N = 200 PRISON II	totally occluded arteries TLR after 3 years TVR after 3 y ears	 7% 11%	 27% 30%	 RD 20% NNT 5 RD 29% NNT 3
	Suttorp (2006) SAME POPULATION as Rahel	RCT N = 200 PRISON II	TLR at 6 months	4%	19%	RD 15% NNT 7
low level of evidence	**Werner (2004)**	Retrospective - matched Cohort N = 96	CTO Repeat PCI Binary restenosis DES 8.3%, BMS 51.1% Re-occlusions DES 2.1%, BMS 23.4% Higher target vessel failure with BMS vs. Taxus in DM and non DM	 5.3%	 31.9%	 26.6%
	Colombo (2007)	Review article, not systematic review or meta Contains information from Werner, Suttorp	Includes RCTS with non randomized studies Quotes re-stenosis rates for PRISON II for DES (11%) and BMS (41%) Unclear, appears to quote DES TLR fand from 3.3% - 10%	NR	NR	

Saphenous vein graft

	Author	Design	Population	DES	BMS	Effect size
Highest	**NONE**					
Next level	**RCTS**					
	Brilakis (2009)	RCT SOS trial PES vs.BMS median f/u 1.5	N = 80 (112 lesions, 88 SVG) Binary Restenosis (angiographic) – PES 9%, BMS 51%			 RD (NNT)

		yrs	TLR (? at last f/u?) TVR (? at last f/u?)	5% 15%	28% 31%	23% (4) 16% (6)
	Vermeersch (2007)	RCT RRISC Trial	N = 75 (96 SVG lesions) F/u to 3 years (outcomes as of last f/u) TLR TLR –lesions based TVR TVR – lesion based	 24% 19% 34% 36%	 30% 26% 38% 41%	diffs not stat signif RD (NNT) 6% (17) 5% 4% (25) 5% (20)
low level of evidence	**Chu (2005)**	Retrospective Cohort; not concurrent controls? ? no control for confounding?	N = 98 pts (114 SVG lesions) 6 months TLR TVR 1 year TLR TVR	 2% 4% 6% 13%	 7% 11% 7% 11%	 RD 5% 7% 1% 2% Diffs not stat sig

Overall Length of Stent [AND/OR VESSEL OR STENT DIMENSIONS]

	Author	Design	Population	DES	BMS	Effect size

	Stone (2004) **[used in Canadian decision]**	RCT Sub analysis for 9 month angiographic restenosis in analysis segment	N = 558 pts who had angiographic evaluation and for whom severity of stenosis could be evaluated – RATE OF ANGIOGRAPHIC RESTENOSIS Ref vessel diam ≤2.5 mm >2.5 - <3.0mm ≥ 3.0 mm Max stent diam 2.5mm 3.0mm 3.5 mm Lesion length ≤ 10 mm >10 - ≤ 20mm ≥ 20 mm Total stent length 16mm 24 mm ≥32 mm	 10.2% 6.7% 6.8% 8.8% 9.1% 5.5% 5.6% 7.2% 14.9% 7.2% 6.4% 10.3%	 38.5% 27.8% 15.2% 40.8% 31.2% 12.9% 18.9% 25.8% 41.5% 20.8% 28.9% 37.3%	 <u>RD (NNT); stat sig</u> 28.3 (3.5) Sig 21.1 (4.7) Sig 8.4 (11.9) NS 32.0 (3.1) Sig 22.1 (4.5) Sig 7.4 (13.5) NS 13.3 (7.5) Sig 18.6 (5.4) Sig 26.6 (3.8) Sig 13.6 (7.4) Sig 22.5 (4.4) Sig 27.0 (3.7) Sig NS = not statistically significant
	TU (2007) **Ontario**	Population based registry study N = 3751 small vessel < 3mm, large ≥ 3 mm Lesion length short <20 mm long ≥ 20 mm	Matched cohort analysis –TVR <u>Vessel Lesion N pairs</u> DM < 3 mm ≥ 20 mm 347 < 3 mm <20 mm 253 ≥ 3 mm ≥ 20 mm 295 ≥ 3 mm <20 mm 291 NON-DM < 3 mm ≥ 20 mm 782 < 3 mm <20 mm 502 ≥ 3 mm ≥ 20 mm 638 ≥ 3 mm <20 mm 505	 7.2% 4.7% 6.1% 6.2% 8.6% 6.8% 5.6% 5.3%	 17.6% 13.0% 10.5% 7.6% 12.3% 8.0% 7.5% 5.9%	 <u>RD (NNT- author)</u> 10.4 (10) Sig 8.3 (12) Sig 4.4 (23) Sig 1.4 (71) NS 3.7 (27) Sig 1.2 (83) NS 1.9 (53) NS 0.6 (167) NS

	Pfisterer (2009) (Appendix)	Sub-analysis of BASKET † (prospective cohort)	N = 826 69% multi-vessel disease 29% CTO Evaluate small vs. large stent			lowest NNT ~1-11 pts
						RD =
			Non-MI TVR	9.9%	13.9%	4.0%
			small stent	10.7%	19.8%	9.1%
			large stent	9.5%	11.5%	2.0%
			Any TVR	14.7%	17.5%	2.8%
			small stent	16.5%	25.9%	9.4%
			large stent	14.0%	14.1%	0.1%
low level of evidence	**James (2009)*** (From HTCC presentation)	SCAAR registry study	Restenosis- at 1 year, 1 stent group (DES n = 12,358, BMS n = 8649)			Lowest NNT ~12
						RD =
			Overall	2.9%	4.4%	1.5%
			Stent size			
			< 3mm diam	3.2%	6.8%	3.6%
			≥ 3mm diam	2.6%	3.6%	1.0%
			< 20 mm length	2.6%	4.2%	1.6%
			≥ 20 mm length	3.3%	5.1%	1.8%
			Stable Angina	2.8%	4.7%	1.9%
			Unstable Angina	3.1%	4.6%	1.5%
			STEMI	2.7%	4.1%	1.4%
			Non DM	2.7%	4.3%	1.6%
			(Stent dimension)			
			≥ 3mm diam, <20mm long	2.4%	3.5%	1.1%
			≥ 3mm diam, ≥20mm long	2.6%	3.7%	1.1%
			< 3mm diam, <20mm long	2.4%	5.9%	3.5%
			< 3mm diam, ≥20mm long	3.5%	10.1%	6.6%
			DM	3.6%	5.0	1.4%
			(stent dimension)			
			≥ 3mm diam, <20mm long	2.1%	3.5%	1.4%
			≥ 3mm diam, ≥20mm long	4.4%	5.4%	1.0%
			< 3mm diam, <20mm long	4.3%	6.1%	1.8%
			< 3mm diam, ≥20mm long	4.3%	12.6%	8.3%

Non-randomized studies from HTA

1. Brodie BR, Stuckey T, Downey W, et al. Outcomes with drug-eluting stents versus bare metal stents in acute ST-elevation myocardial infarction: results from the Strategic Transcatheter Evaluation of New Therapies (STENT) Group. *Catheter Cardiovasc Interv.* Dec 1 2008;72(7):893-900.

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APPENDIX B: Reference List: Articles suggested or cited by committee members
Selection and suggestedarticles was not based on a formal systematic search or review of literature and formal critical appraisal was not performed. No restrictions on inclusion or exclusion of articles were set *a priori*. The process was not intended to provide a comprehensive evaluation.

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Health Technology Clinical Committee Findings and Coverage Decision

Topic: Cardiac Stent
Meeting Date: May 8, 2009
Final Adoption:

Number and Coverage Topic

20090508A – Cardiac Stent: Drug Eluting Stents (DES) and Bare Metal Stents (BMS) for the treatment of coronary artery disease.

HTCC Coverage Determination

Cardiac Stent is a **covered benefit with conditions** consistent with the criteria identified in the reimbursement determination**.**

HTCC Reimbursement Determination

❖ Limitations of Coverage

1) Bare Metal Stents are covered without conditions.
2) Drug eluting stents are conditionally covered, for patients with high risk of revascularization only, defined as:
    a. Vessel diameter of less than 3 mm,
    b. Lesions longer than 15 mm, or
    c. Patients with diabetes mellitus.

❖ Non-Covered Indicators

Drug eluting stents are not covered for other indications.

❖ Agency Contact Information

Agency	Contact Phone Number
Labor and Industries	1-800-547-8367
Public Employees Health Plan	1-800-762-6004
Health and Recovery Services Administration	1-800-562-3022

P.O. Box 42712 • Olympia, Washington 98504 • www.hta.hca.wa.gov • 360-923-2742 • FAX 360-923-2766 • TTY 360-923-2701

Health Technology Background

The Cardiac Stent topic was selected and published in August 2007 to undergo an evidence review process. Heart disease is the leading cause of death and disability in US: with 700,000 deaths. The most common heart disease in the US is coronary artery disease (CAD), which can lead to heart attack. CAD is a narrowing of one or more coronary arteries that result in an insufficient supply of oxygen to the heart muscle and is a leading cause of death in the US and developed countries. CAD may be asymptomatic or lead to chest pain (angina), heart attack, myocardial infarction (MI) or death. Prediction of which patients with CAD will have serious versus no or a mild symptom remains difficult.

Treatments include:

- Manage and reduce risk factors, such as: smoking, obesity, high blood pressure and cholesterol.
- Medication therapy – beta blockers, nitrates, statins, antiplatelet agents and calcium channel blockers.
- Surgical treatment by mechanically opening the artery with a catheter with or without stent (percutaneous coronary intervention – PCI) and bypass surgery.

Use of PCI has steadily risen over past decade while bypass remains relatively unchanged. PCI accounts for over 60% of surgical treatment. Unanswered questions remain about best use of each option, when and for what patient. Cardiac Stents are small tubes placed in an artery to keep it open. Stents are either not coated (bare metal stents) or coated with a drug (drug eluting stents). Cardiac Stent potential advantages: physically opening the artery and being less invasive than bypass surgery. Cardiac Stent potential disadvantages: targeted solution to widespread disease, unclear protocols, clotting and re-operation. Important, unanswered questions remain about whether, when, and what type of stent placement is appropriate versus other medical management or surgery.

In March 2009, the HTA posted a draft and then followed with a final report from a contracted research organization that reviewed publicly submitted information; searched, summarized, and evaluated trials, articles, and other evidence about the topic. The comprehensive, public and peer reviewed, Cardiac Stent report is 175 pages, identified 304 potentially relevant citations; 10 previous health technology assessments or similar reports; 12 meta-analyses or pooled analysis, one of which was of non-randomized studies; 13 reports of long-term follow-up or sub-analyses to previous RCTs or new RCTs found; 26 non-randomized or registry studies and 1 full economic study and one systematic review.

An independent group of eleven clinicians who practice medicine locally meet in public to decide whether state agencies should pay for the health technology based on whether the evidence report and other presented information shows it is safe, effective and has value. The committee met on May 8th, reviewed the report, including peer and public feedback, and heard public and agency comments. Meeting minutes detailing the discussion are available through the HTA program or online at http://www.hta.hca.wa.gov in the committee section.

Committee Findings

Having considered the evidence based technology assessment report and the written and oral comments, the committee identified the following key factors and health outcomes, and evidence related to those health outcomes and key factors:

1. Evidence availability and technology features

The committee finds the following key factors relevant to the coverage decision:

1.1 The evidence based technology assessment report indicates that Coronary Artery Disease (CAD), a narrowing of the arteries that supply the heart with oxygen, is very common and is an important public health concern. Prediction of risk of serious complication is difficult: while the location and severity of obstructions are used, they do not always correlate with symptoms or outcome.

1.2 Treatment options for CAD to open the arteries include medical therapy and lifestyle management, percutaneous coronary intervention (PCI) a catheter with or without stenting, and coronary artery bypass grafting (CABG). Catheter based interventions that leave a stent to hold open the arteries can include bare metal stents (BMS) or drug eluting stents (DES).

1.3 The committee found that there was a large amount of randomized and observational studies available comparing DES and BMS on many of the important health outcomes they identified for stents. The committee relied most heavily, as did the evidence based technology assessment report, on one recent meta analysis of 38 trials including 18,000 patients, and summarized information from five previous health technology assessments, most conducted with their own meta-analysis, and one focusing on registry studies

1.4 The committee also considered additional evidence published after the draft and final evidence report. The final evidence report includes a brief summary of the study published after the draft which linked Medicare data with ACC registry data, *Douglas*, et. al. An uncorrected proof of this registry study contained summary information on data of 260,000 over 65 year old Medicare patients for up to 30 months. Two additional study abstracts were published one day prior to the meeting. The studies were briefly reviewed by the evidence review vendor and made available to committee members. First, a registry follow-up study from Sweden (*SCAAR 2*) on 47,967 patients through 2006 that were followed from one to five years. A second randomized trial, *Stone, et al*, of 3006 patients comparing BMS and DES in patients with ST-segment elevation myocardial infarction.

2. Is the technology safe?

The committee found that stent thrombosis was the most significant safety outcome measure, and discussed briefly bleeding and stent fracture. The report identified the following evidence:

2.1. The evidence based technology assessment report indicated that stent thrombosis is a rare, but serious complication (generally occurring in about 1.5% of cases) with potentially higher rates in DES. This topic prompted a review of evidence by an FDA panel in 2006 that concluded DES used for approved indications (single, new lesion of certain size) and with anti-platelet therapy is prescribed for at least 1 year (instead of 3 to 6 months) were safe. From the most recent meta-analysis with four year follow up, thrombosis rates are low and not statistically different: 1.4% SES; 1.7%PES and 1.2%BMS; though the evidence review indicates that even large studies may be underpowered to detect statistically significant differences.

2.1.1. The evidence based technology assessment report summarized seven HTA's, including one HTA of registry data: most concluded no statistically significant difference, though

several indicated they may be underpowered, three reported there was a higher risk of stent thrombosis with DES.

2.1.2. The evidence based technology assessment also included a summary from Stettler's more recent meta-analysis of randomized trials related to thrombosis (included 24 trials and 12,973 patients which showed an overall rate of thrombosis at 1.4% and no statistically significant difference between BMS and DES in up to four years, though some statistical differences were observed in subgroups comparing SES, PES and BMS and short versus longer time periods. Adherence and length of anti-platelet therapy are not well documented in trials, though a 2008 Stettler updated meta-analysis found no statistically significant difference in thrombosis rates, regardless of anti-platelet therapy regimen.

2.2. Stent Thrombosis in special populations (diabetics and acute MI): Most HTA's and the Stettler meta-analysis in specific subpopulations generally reported no statistically significant difference between BMS and DES in stent thrombosis rates. One HTA noted patients more likely to benefit from DES to be diabetic patients, small vessels, and chronic kidney disease, were at the same time at higher risk for developing late stent thrombosis. Although, one HTA of registry data indicated higher in-stent thrombosis with DES (2.4 to 4.4%) versus BMS (0.8%).

2.3. Bleeding and Stent Fracture: the evidence based technology assessment report reviewed these safety issues, however no randomized studies or HTA's compared DES to BMS for this outcome. One non-randomized study compared different DES patients, with overall rates of bleeding at 3.1%, patients on dual antiplatelet use and over age 65 were significant risk factors for major bleeding in DES patients.

3. Is the technology effective?

The committee found that there were four key health outcomes that were most significant in assessing the technology's effectiveness. The report identified the following evidence:

3.1. Freedom from Overall and Cardiac Mortality:

3.1.1. The evidence based technology report includes death, and specifically cardiac-related death, as a key health outcome in treatments for cardiac artery disease and core evidence indicates no difference between DES and BMS. It was noted both by the evidence review and committee members that the updated FDA recommendation to continue dual anti-platelet therapy for one year in DES patients may be a related factor that was not separately reported in many studies.

3.1.2. The evidence review of previous HTA and the meta-analysis report no statistically significant difference in overall or cardiac mortality between DES and BMS up to four years.

3.1.3. Studies including registry data cite the SCAAR (Sweeden) where authors found increased risk of death with DES at 6 months and 3 years (relative risk of 1.18%). In other registry studies, the findings were mixed, with six suggesting no difference; and three showing higher BMS risk.

3.1.4. Freedom from mortality in elderly subpopulation. The Douglas study (not critically appraised) of Medicare patients indicates a 3% higher risk of mortality from BMS than DES.

3.1.5. Freedom from mortality in acute MI subpopulation. The evidence based technology report summarized results from one recent HTA, a meta-analysis and three recent RCT's that concluded no statistically significant difference in DES and BMS groups with acute MI for mortality.

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3.1.6. Freedom from mortality in diabetics subpopulation. The evidence based technology report indicates that diabetics tend to have multi-vessel disease, smaller coronary arteries, and longer lesions. Previous HTAs had only limited evaluation of diabetics, but recent meta-analysis reported a two fold increase in mortality for diabetic patients receiving less than 6 months of dual anti-platelet therapy. Three recent meta-analyses indicate that the overall mortality risk is similar between BMS and DES.

3.2. Freedom from MI

3.2.1. The evidence based technology report and committee agreed that subsequent myocardial infarction (MI or heart attack) is a key health outcome in treatments for cardiac artery disease, including stents and core evidence indicates no difference between DES and BMS.

3.2.2. The evidence review of previous HTAs , the Stettler meta-analysis and two other meta-analyses report no statistically significant difference in MI between DES and BMS in trials with two to five years follow up. One meta-analysis with follow up at 6 to 12 months reported lower MI with DES (3.3%) than BMS (4.2%).

3.2.3. Freedom from MI in diabetics subpopulation. The evidence based technology report focused on the recent meta-analysis with up to four years follow up indicating no difference in MI outcomes between BMS and DES diabetic patients.

3.2.4. Freedom from MI in acute MI subpopulation. The evidence based technology report focused on the recent meta-analysis with up to four years follow up indicating no difference in MI outcomes between BMS and DES in acute MI patients.

3.2.5. Freedom from MI in elderly subpopulation: The evidence report summarized the Douglas study (not critically appraised) finding a higher rate of MI (1.4% risk difference) in BMS patients.

3.3. Freedom or reduction of Target vessel revascularization/target lesion revascularization (TVR)

3.3.1. The evidence based technology report and committee agreed that TVR, or repeat procedures to open the same vessel, is a key health outcome in stent comparisons and that DES results in 11% fewer TVR than BMS.

3.3.2. The committee discussed the implication of dual anti-platelet therapy and whether that impacts revascularization rates.

3.3.3. The evidence review of previous HTAs, the Stettler meta-analysis and two other meta-analyses report a lower rate of TVR using DES compared to BMS. The Stettler meta-analysis reported a revascularization rate of DES at 6.9% to 9.0% and BMS at 19.0% with up to 4 year's follow up – this represents an 11.1% reduction.

3.3.4. Revascularization rates in studies of the Acute-MI subpopulation also reported decreased revascularization using DES (4.8% to 5.1%) versus BMS (12.0% to 13.1%).

3.3.5. Revascularization rates in HTA's and meta-analysis of the diabetic subpopulation also reported significant decreased revascularization using DES, regardless of use of dual anti platelet therapy, out to one year DES (6.3% to 11.3%) versus BMS (19.3% to 31.1%).

3.3.6. Revascularization rates in studies of the elderly subpopulation reported a no difference in revascularization rate between DES (23.5%) and BMS (23.4%) at 30 months.

3.4. Quality of Life

3.4.1. The evidence based technology report included quality of life as a key outcome, but studies did not report or define this measure. The committee commented that quality of life is important and future studies should include this outcome. Additionally, TVR is a part of a quality of life where less need for re-surgery would be positive but the metric is incomplete and it appears that short term results may favor DES but longer term results are similar.

4. Is the technology cost-effective?

The committee found that there was key information about cost and value:

4.1. There remains uncertainty regarding efficacy, effectiveness, and safety of DES versus BMS and differing assumptions contribute to variability in cost analysis. The incremental cost effectiveness ratios (ICER) were most influenced by the price premium of DES.

4.2. The evidence included 43 cost effectiveness studies, but focused on evidence from previous HTA's which concluded that DES might be cost effective in higher risk patients and not cost-effective with low risk patients; when more realistic assumptions and data values were used, DES may be cost effective only under very limited circumstances, and several studies were industry supported.

4.3. Price premium for DES in HTA's ranged from $563 Euro to $1,299. ICER for use of DES ranged from a low of $27,540 to a high of $1,099,858 QALY; with the four economic analyses performed as part of HTA's ranging from $64,394 to over 1 million Euros. ICER's for repeat revascularizations ranged from $1,650 to $7,000.

4.4. Washington state use data from the COAP database which gathers information on all WA procedures, from 2004 to 2007, BMS was used 15% and DES 85%.

4.5. State agency cost data: Utilization at the three agencies over the same time period is 15% BMS and 83% DES.

Committee Conclusions

Having made findings as to the most significant and relevant evidence regarding health outcomes, key factors and identified evidence related to those factors, primarily based on the evidence based technology assessment report, the committee concludes:

5. Evidence availability and technology features

The committee concludes that the best available evidence on cardiac stents has been collected and summarized, and the overall quality of this evidence is high and robust as follows:

5.1. There was a large amount of high quality, randomized and observational studies available comparing DES and BMS on many of the important health outcomes they identified for stents. The committee relied most heavily on a recent meta analysis of 38 trials including 18,000 patients, and summarized information from five previous health technology assessments.

5.2. Randomized or well designed controlled trials provide the highest level of confidence for proving efficacy, especially with adequate participants, assessment of all patient centered health outcomes, and for sufficient duration. The very recent registry studies may provide additional information (e.g. rare complications and additional subpopulation data) but should not be relied upon as the basis to overturn the RCT results. Recently published articles not included in critical appraisal were considered, but would not be relied upon for final determination without seeking additional review by evidence vendor.

5.3. Heart disease is a burdensome condition with potentially significant and life threatening outcomes. It is widespread condition with imprecise measures of those at risk for life threatening outcomes and thus is a significant health concern to ensure the right treatment for those at high risk as well as low risk.

5.4. Many treatments, including non-invasive treatments, are covered by agencies. The type of stent selected (issue for current review) does not have an effect on mortality or heart attack –

the two potentially life threatening outcomes, but may impact need for revascularization need and cost.

6. Is it safe?

The committee concludes that the comprehensive evidence reviewed shows that the DES and BMS have been proven equally safe. Key factors to the committee's conclusion included:

6.1. *Morbidity related to Stent Thrombosis:* The committee agreed with the evidence report conclusions that these are rare events, where even the larger RCT's and observational data may not be powered to detect. However, the best available meta analysis of RCT data shows difference relied heavily on the most recent meta-analysis with four year follow up: 1.4% SES; 1.7%PES and 1.2%BMS.

6.2. *Bleeding:* the committee concluded that bleeding is a very serious complication. Due to dual anti-platelet therapy proscribed with DES, this complication could be higher in DES; but not enough information and registry data, though lower quality, showed equivalence with 3.4% BMS vs 3.6% DES rate.

6.3. *Stent Fracture:* The committee agreed that this issue was not applicable since evidence was not obtainable on this outcome and no other reason to believe rates between the two stent types would be different.

7. Is it effective?

The committee concludes that the comprehensive evidence reviewed shows that the DES technology has been proven equally effective to BMS, and more effective than BMS in one area:

7.1. The committee identified four key health outcomes that impacted effectiveness; with three have high quality evidence available.

7.2. *Freedom from Cardiac Mortality:* the committee concluded that data from multiple RCTs demonstrated that there is no overall or cardiac related benefit with DES compared to BMS.

7.3. *Freedom from Myocardial Infarction (MI):* the committee concluded that the data from multiple RCTs demonstrated that there is no benefit from DES compared to BMS in reducing rates of MI.

7.4. *Freedom or reduction of revascularization (TVR):* the committee concluded that data from multiple RCTs demonstrates a benefit of an 11% reduction in the rate of revascularization with use of DES compared to BMS.

7.5. *Quality of Life:* the committee believes that quality of life is an important health outcome to demonstrate overall effect of treatment, but concluded that there was not reliable data to conclude whether DES provided a benefit over BMS. The committee discussed the previous revascularization reduction as a component of quality of life

8. Is it cost-effective?

The Committee concludes that the comprehensive evidence review shows that the DES technology is less cost-effective overall. However, the committee also addressed cost-effectiveness in a certain situation, for high risk patients, and was split with five finding that DES were more cost effective and five finding that DES was unproven or less cost-effective for this population.

8.1. The committee noted that the evidence review contained multiple cost effectiveness studies and agreed that the most important factors were the cost premium for DES, but also discussed the cost of medications, revascularization cost, issue of lack of ability to

demonstrate higher overall efficacy, and the concept of measuring DES in terms of cost per revascularization versus cost per QALY (which takes revascularization and other factors into account).

8.2. The committee agreed that overall, DES is not cost-effective, especially considering the state's $3,600 differential, where lower price premiums produced staggering cost per QALYs.

8.3. For certain subpopulations of high risk patients, some HTAs reported, and five committee members agreed that DES is cost-effective.

9. Medicare Decision and Expert Treatment Guidelines

The committee deliberations included a discussion of National Medicare Decisions and expert treatment guidelines, and an understanding that the committee must find substantial evidence to support a decision that is contrary. RCW 70.14.110. Based on the following, the Committee concludes that a decision consistent with two expert treatment guidelines and contrary to the National Medicare Coverage Decision and one treatment guideline is justified:

9.1. Centers for Medicare and Medicaid Services (2008) – there is no national coverage decision (NCD) relating to drug eluting versus bare metal stents. There is coverage memo on percutaneous intervention overall (PTA) which covers treatment with conditions: PTA (with and without a placement of a stent) is covered when used in accordance with FDA approved protocols for treatment of atherosclerotic lesions of a single coronary artery for patients for whom the likely alternative treatment is coronary bypass surgery and who exhibit the following characteristics: (1) angina refractory to optimal medical management; (2) objective evidence of myocardial ischemia; and (3) lesions amenable to angioplasty.

9.2. Guidelines -- No guidelines for clinical care or appropriateness have been published regarding the use of BMS versus DES. The most comprehensive guideline, a joint ACC/AHA guideline addresses broader perspectives on setting and issues involved in the decisions leading to coronary stent placement as well as other treatments.

9.3. Two other organizations, England's NHS and Ontario's OHTAC have recommendations for use of DES in narrow lesions (<3.0 or 2.75mm) long lesions (>15 or 20 mm). Patients with diabetes and a price differential cap of $300 pounds are additional limits.

Committee Decision

Based on the deliberations of key health outcomes, the committee decided that it had the most complete information: a comprehensive and current evidence report, public comments, additional just published studies, input from a clinical expert, and agency and state utilization information. The committee concluded that the current evidence on Cardiac Stents demonstrates that there is sufficient evidence of a health benefit to cover the use of cardiac stents, but limit the use of Drug eluting stents to certain circumstances. The committee considered all the evidence and gave greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable. The committee found that drug eluting stents were proven to be equivalent to bare metal stents in safety and efficacy overall. The committee found that drug eluting stents were proven to be more effective in one area: reducing revascularization, and were proven to cost more.

Based on these findings, the committee voted to continue coverage for bare metal stents and voted 8 to 2 to cover drug eluting stents, with conditions: limited to patients with highest risk of revascularization (less than 3 millimeter vessel, or lesion longer than 15 millimeters, or diabetics).

Health Technology Clinical Committee Authority

Washington State's legislature believes it is important to use a scientific based, clinician centered approach for difficult and important health care benefit decisions. Pursuant to chapter 70.14 RCW, the legislature has directed the Washington State Health Care Authority, through its Health Technology Assessment program to engage in a process for evaluation process that gathers and assesses the quality of the latest medical evidence using a scientific research company and takes public input at all stages. Pursuant to RCW 70.14.110 a Health Technology Clinical Committee (HTCC) composed of eleven independent health care professionals reviews all the information and renders a decision at an open public meeting. The Washington State Health Technology Clinical Committee (HTCC), determines how selected health technologies are covered by several state agencies. RCW 70.14.080-140. These technologies may include medical or surgical devices and procedures, medical equipment, and diagnostic tests. HTCC bases their decisions on evidence of the technology's safety, efficacy, and cost effectiveness. Participating state agencies are required to comply with the decisions of the HTCC. HTCC decisions may be re-reviewed at the determination of the HCA Administrator.

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