Drug-eluting stents:

a systematic review & economic evaluation

4 Addendum

Confidential: not for release

No commercial in confidence data have been included in the preparation of this report March, 26, 2007



NICE TAR 04/42 - Addendum to version 03

Report commissioned by: NHS R&D HTA Programme

On behalf of: The National Institute for Health and

Clinical Excellence

Produced by: Liverpool Reviews and Implementation

Group

Sherrington Buildings University of Liverpool

Ashton Street Liverpool, UK L69 3GE

Tel: +44 (0) 151 794 5682/5541/5067

Fax: +44 (0) 151 794 5585 Email: LRiG@liv.ac.uk

Addendum - additional evidence and analyses

Sensitivity Analysis Tables for Drug-Eluting Stent Appraisal including Additional Use of Clopidogrel

Recent controversy in cardiology conferences and journals has centred on claims by some researchers of accumulating evidence of increased rates of late stent thrombosis with associated sequelae (possibly including mortality) arising from use of drug-eluting stents. Although the issues are not yet resolved, the FDA have suggested that extended use of anti-thrombolytics should be considered, and the American Heart Association has issued precautionary guidelines that clopidogrel should be prescribed for at least 12 months post-PCI. The British Cardiovascular Intervention Society (BCIS) council produced similar guidance at its autumn 2006 meeting:

"....Patients should be advised to continue dual anti-platelet therapy for one year following DES placement with some individual cases being advised to continue in the long term."

NICE have indicated that it is important to explore the implications of these developments for the cost-effectiveness of drug-eluting stents in the UK, prior to issuing updated guidance. To this end NICE requested that the analyses previously provided to the Appraisal Committee in Addendum 3 and Addendum supplement 3 to the LRiG Technology Assessment Report be updated on the assumption that clopidogrel use would be extended in patients receiving drug-eluting stents from 3 months to 12 months post-intervention.

Clopidogrel is normally prescribed as a single daily oral dose of 75mg costing £35.31 per 28 tablet pack (BNF 52, February 2007). This is equivalent to £460.61 per year, and results in an extra cost per DES patient of £345.45 for an additional 9 month period. It should be noted that bleeding complications associated with the use of clopidogrel have not been taken account of in these sensitivity analyses.

Selected updated tables from Addendum supplement 3 are shown below (using the same identifiers to allow ready comparison with the earlier results). In addition, the initial descriptive Table A from Addendum supplement 3 is repeated at the request of NICE.

Explanatory Notes

Initial Descriptive Table A

- 1. The descriptive table has been prepared using Liverpool CTC audit patient-level data, and the multi-variate model using conventional factors described in the Addendum supplement. This is necessary as no equivalent IPD unselected dataset is currently available to LRiG on which the required analysis could be performed. Readers should bear in mind that none of the three factors in this multi-variate model achieved conventional significance so that the individual relative risks have wide confidence intervals and should be considered as only illustrative.
- 2. Results for absolute risks and average numbers of stents are simple unadjusted means for all relevant patients. Minor differences from figures previously published are due to the exclusion of some non-elective patients not considered eligible for this review (those for whom PCI was primary treatment for AMI), and to bias adjustments required to previous estimates which made use of non-linear regression techniques.
- 3. Sub-groups are ordered by increasing size of the relative and absolute risks. The average risks obtained in CTC data set are shown as an additional bold column (marked Base Case) for information.

Tables (B, C, F & G)

- 4. The tables have been prepared on the basis of the adjustments identified in the Addendum supplement:
- stent wastage rates of 1%;
- alternate disutility estimates for PCI (0.00304 per patient) and CABG (0.03808);
- adjustments, for reduced numbers of non-fatal AMIs, to costs (saving of £13 per patient) and utility (gain of 0.00055 per patient) when DES are used.
- 5. For Tables B and F, the mean number of stents used, and the mean repeat intervention rate for the whole patient group are used. However, in Tables C and G, the emboldened absolute risks are calculated specifically for the sub-groups of CTC patients in whom only one index stents was deployed.

- 6. The threshold premium in the final column of the tables is the maximum value of the price premium which would yield an ICER of £30,000 per QALY gained or less.
- 7. The final row shows the effect on estimated cost-effectiveness for the Base Case of including a direct benefit from reduced mortality associated with performing repeat interventions. These calculations are made on the following assumptions:
- average CTC proportions of reinterventions by CABG apply (9.0% elective, 17.9% non-elective);
- additional mean life expectancy for patients surviving without reintervention of 10 years;
- mean utility value of patients in such additional life-years of 0.66.

It should be borne in mind that this adjustment depends upon a strong presumption of effect for which there is no direct evidence. It is LRiG's view that such an adjustment is unwarranted and probably involves 'double-counting' of deaths already included in aggregate trial results.

NICE TAR 04/42 - Addendum to version 04

Table A: Parameter values for risk-based subgroups, derived from Liverpool CTC audit data

Elective patients

								Reintervention rate at 12 months									
Conve	Conventional risk factors							Absolute risk									
			Share of	Mean													
Long	Small		elective	stents			Relative	6%	7%	7.43%	8%	9%	10%	11%	12%	13%	
lesion	vessel	Diabetes	caseload	used	LCL	UCL	risk										
No	No	No	59.7%	1.54	1.49	1.58	1.00	5.3%	6.1%	6.5%	7.0%	7.9%	8.8%	9.7%	10.5%	11.4%	
Yes	No	No	22.5%	1.63	1.55	1.72	1.20	6.3%	7.4%	7.8%	8.4%	9.5%	10.5%	11.6%	12.6%	13.7%	
No	No	Yes	8.5%	1.56	1.43	1.69	1.38	7.3%	8.5%	9.0%	9.7%	10.9%	12.1%	13.3%	14.5%	15.8%	
No	Yes	No	3.8%	2.30	2.11	2.48	1.52	8.0%	9.3%	9.9%	10.7%	12.0%	13.3%	14.7%	16.0%	17.4%	
Yes	No	Yes	4.0%	1.72	1.52	1.91	1.66	8.7%	10.2%	10.8%	11.6%	13.1%	14.5%	16.0%	17.5%	18.9%	
Yes	Yes	No	0.9%	2.53	2.19	2.87	1.82	9.6%	11.2%	11.9%	12.8%	14.4%	16.0%	17.6%	19.2%	20.8%	
No	Yes	Yes	0.6%	2.67	2.23	3.11	2.10	11.1%	12.9%	13.7%	14.7%	16.6%	18.4%	20.3%	22.1%	23.9%	
Yes	Yes	Yes	0.1%	3.00	ne	ne	2.52	13.3%	15.5%	16.4%	17.7%	19.9%	22.1%	24.3%	26.5%	28.7%	
	Overall		100.0%	1.615	1.580	1.650				Base case							

Patients affected by factor

27.4% 5.4% 13.2%

ne not estimable

Non-Elective patients

							Reintervention rate at 12 months										
Conve	entional risk	factors									P	Absolute risl	<				
			Share of non-	Share of non- Mean													
Long	Small		elective	stents			Relative	8%	9%	10.04%	11%	12%	13%	14%	15%	16%	
lesion	vessel	Diabetes	caseload	used	LCL	UCL	risk										
No	No	Yes	8.0%	1.52	1.34	1.69	0.90	6.5%	7.3%	8.2%	9.0%	9.8%	10.6%	11.4%	12.2%	13.0%	
No	No	No	60.1%	1.43	1.37	1.50	1.00	7.2%	8.1%	9.1%	10.0%	10.9%	11.8%	12.7%	13.6%	14.5%	
Yes	No	Yes	4.5%	1.54	1.29	1.79	1.07	7.8%	8.7%	9.7%	10.7%	11.6%	12.6%	13.6%	14.5%	15.5%	
Yes	No	No	23.7%	1.42	1.33	1.52	1.19	8.6%	9.7%	10.8%	11.9%	12.9%	14.0%	15.1%	16.2%	17.2%	
No	Yes	Yes	0.2%	2.00	ne	ne	2.36	17.1%	19.2%	21.4%	23.5%	25.6%	27.8%	29.9%	32.0%	34.2%	
No	Yes	No	2.5%	2.00	1.51	2.49	2.62	19.0%	21.4%	23.8%	26.1%	28.5%	30.8%	33.2%	35.6%	38.0%	
Yes	Yes	Yes	0.2%	2.00	ne	ne	2.81	20.3%	22.9%	25.5%	27.9%	30.5%	33.0%	35.6%	38.1%	40.7%	
Yes	Yes	No	0.7%	2.50	1.40	3.60	3.12	22.6%	25.4%	28.3%	31.1%	33.9%	36.7%	39.5%	42.3%	45.2%	
	Overall		100.0%	1.467	1.415	1.518				Base case			_				

Patients affected by factor

29.1% 3.7% 12.9%

ne not estimable

Table B: All Elective Patients, using mean number of stents implanted

£542

£382

£702

£862

£1,022

£1,182

£1,342

Elective In	dex PCI	1.615	stent per pa	atient														
																		Threshold
Absolute	Incremental			Increment	al cost by le	evels of price	e premium						cost per QAL		f price premi			premium
risk	utilty	£100	£200	£300	£400	£500	£600	£700	£800	£100	£200	£300	£400	£500	£600	£700	£800	(£30000)
4%	0.00162	£434	£596	£757	£919	£1,080	£1,241	£1,403	£1,564	£268,600	£368,500	£468,300	£568,200	£668,000	£767,900	£867,700	£967,600	-£140
5%	0.00188	£419	£580	£741	£902	£1,063	£1,224	£1,385	£1,546	£222,500	£307,900	£393,400	£478,900	£564,400	£649,900	£735,400	£820,900	-£126
6%	0.00215	£404	£564	£725	£885	£1,046	£1,207	£1,367	£1,528	£187,700	£262,400	£337,100	£411,800	£486,500	£561,200	£635,900	£710,600	-£112
7%	0.00242	£388	£549	£709	£869	£1,029	£1,189	£1,349	£1,510	£160,700	£227,000	£293,200	£359,500	£425,800	£492,000	£558,300	£624,600	-£98
7.43%	0.00253	£382	£542	£702	£862	£1,022	£1,182	£1,342	£1,502	£150,800	£213,900	£277,100	£340,300	£403,500	£466,700	£529,900	£593,000	-£92
8%	0.00268	£373	£533	£693	£852	£1,012	£1,172	£1,332	£1,491	£139,000	£198,500	£258,100	£317,600	£377,100	£436,700	£496,200	£555,700	-£84
9%	0.00295	£358	£517	£676	£836	£995	£1,154	£1,314	£1,473	£121,200	£175,300	£229,300	£283,300	£337,300	£391,300	£445,300	£499,300	-£70
10%	0.00322	£342	£501	£660	£819	£978	£1,137	£1,296	£1,455	£106,400	£155,800	£205,200	£254,600	£304,000	£353,400	£402,800	£452,200	-£55
11%	0.00348	£327	£486	£644	£803	£961	£1,119	£1,278	£1,436	£93,900	£139,400	£184,900	£230,400	£275,900	£321,400	£366,900	£412,300	-£41
12%	0.00375	£312	£470	£628	£786	£944	£1,102	£1,260	£1,418	£83,100	£125,300	£167,400	£209,600	£251,700	£293,900	£336,000	£378,200	-£26
13%	0.00402	£296	£454	£612	£769	£927	£1,085	£1,242	£1,400	£73,800	£113,000	£152,300	£191,500	£230,800	£270,000	£309,300	£348,500	-£12
14%	0.00428	£281	£438	£596	£753	£910	£1,067	£1,224	£1,382	£65,600	£102,300	£139,000	£175,700	£212,400	£249,100	£285,800	£322,500	£3
15%	0.00455	£266	£423	£579	£736	£893	£1,050	£1,207	£1,363	£58,400	£92,900	£127,300	£161,800	£196,200	£230,700	£265,200	£299,600	£18
16%	0.00482	£250	£407	£563	£720	£876	£1,032	£1,189	£1,345	£52,000	£84,500	£116,900	£149,400	£181,800	£214,300	£246,800	£279,200	£33
17%	0.00508	£235	£391	£547	£703	£859	£1,015	£1,171	£1,327	£46,300	£76,900	£107,600	£138,300	£169,000	£199,600	£230,300	£261,000	£47
18%	0.00535	£220	£375	£531	£686	£842	£998	£1,153	£1,309	£41,100	£70,200	£99,200	£128,300	£157,400	£186,400	£215,500	£244,600	£62
19%	0.00562	£205	£360	£515	£670	£825	£980	£1,135	£1,290	£36,400	£64,000	£91,600	£119,300	£146,900	£174,500	£202,100	£229,700	£78
20%	0.00588	£189	£344	£499	£653	£808	£963	£1,117	£1,272	£32,200	£58,400	£84,700	£111,000	£137,300	£163,600	£189,900	£216,200	£93
21%	0.00615	£174	£328	£482	£637	£791	£945	£1,100	£1,254	£28,300	£53,400	£78,400	£103,500	£128,600	£153,700	£178,800	£203,800	£108
22%	0.00642	£159	£312	£466	£620	£774	£928	£1,082	£1,235	£24,700	£48,700	£72,700	£96,600	£120,600	£144,600	£168,600	£192,500	£123
23%	0.00668	£143	£297	£450	£604	£757	£910	£1,064	£1,217	£21,400	£44,400	£67,300	£90,300	£113,200	£136,200	£159,200	£182,100	£139
24%	0.00695	£128	£281	£434	£587	£740	£893	£1,046	£1,199	£18,400	£40,400	£62,400	£84,400	£106,500	£128,500	£150,500	£172,500	£154
25%	0.00722	£113	£265	£418	£570	£723	£876	£1,028	£1,181	£15,600	£36,700	£57,900	£79,000	£100,200	£121,300	£142,400	£163,600	£170
26%	0.00748	£97	£249	£402	£554	£706	£858	£1,010	£1,162	£13,000	£33,300	£53,700	£74,000	£94,300	£114,700	£135,000	£155,300	£185
27%	0.00775	£82	£234	£385	£537	£689	£841	£992	£1,144	£10,600	£30,200	£49,700	£69,300	£88,900	£108,500	£128,000	£147,600	£201
28%	0.00802	£67	£218	£369	£521	£672	£823	£975	£1,126	£8,300	£27,200	£46,100	£64,900	£83,800	£102,700	£121,600	£140,400	£217
29%	0.00828	£51	£202	£353	£504	£655	£806	£957	£1,108	£6,200	£24,400	£42,600	£60,800	£79,100	£97,300	£115,500	£133,700	£233
with Procedural mortality estimate																		
WILLI FIOCE	uurai iiloitalliy	commate																

-£45

7.43% 0.00381

Table C: Elective patients receiving a single stent

Elective Index PCI 1.0	stent per patient
------------------------	-------------------

Absolute	Incremental			Ingramant	al aget by le	evels of pric	o promium			1		Ingramantal	aget per OAI	V by lovels o	of price premi	um		Threshold premium
risk	utilty	£100	£200	£300	£400	£500	£600	£700	£800	£100	£200	£300	£400	£500	£600	£700	£800	(£30000)
4%	0.00162	£372	£471	£571	£670	£769	£869	£968	£1,067	£230,200	£291,600	£353,100	£414,500	£475,900	£537,300	£598,800	£660,200	-£228
5%	0.00188	£357	£456	£555	£654	£752	£851	£950	£1,049	£189,500	£242,000	£294,500	£347,000	£399,500	£452,000	£504,500	£557,000	-£206
5.53%	0.00202	£349	£447	£546	£645	£743	£842	£941	£1,039	£172,200	£221,000	£269,700	£318,400	£367,200	£415,900	£464,600	£513,300	-£194
6%	0.00215	£342	£440	£538	£637	£735	£834	£932	£1,031	£158,800	£204,600	£250,400	£296,200	£342,000	£387,800	£433,600	£479,400	-£183
7%	0.00242	£326	£424	£522	£620	£718	£816	£915	£1,013	£135,000	£175,500	£216,100	£256,700	£297,300	£337,800	£378,400	£419,000	-£160
8%	0.00268	£311	£409	£506	£604	£701	£799	£897	£994	£115,900	£152,200	£188,600	£225,000	£261,400	£297,800	£334,100	£370,500	-£137
9%	0.00295	£296	£393	£490	£587	£684	£782	£879	£976	£100,200	£133,100	£166,100	£199,000	£232,000	£264,900	£297,900	£330,800	-£114
10%	0.00322	£280	£377	£474	£571	£667	£764	£861	£958	£87,100	£117,200	£147,300	£177,400	£207,500	£237,600	£267,600	£297,700	-£91
11%	0.00348	£265	£361	£458	£554	£650	£747	£843	£939	£76,100	£103,700	£131,400	£159,000	£186,700	£214,400	£242,000	£269,700	-£67
12%	0.00375	£250	£346	£442	£537	£633	£729	£825	£921	£66,600	£92,100	£117,700	£143,300	£168,900	£194,500	£220,100	£245,600	-£43
13%	0.00402	£234	£330	£425	£521	£616	£712	£807	£903	£58,300	£82,100	£105,900	£129,700	£153,400	£177,200	£201,000	£224,800	-£19
14%	0.00428	£219	£314	£409	£504	£599	£694	£790	£885	£51,100	£73,300	£95,500	£117,700	£139,900	£162,100	£184,300	£206,500	£5
15%	0.00455	£204	£298	£393	£488	£582	£677	£772	£866	£44,800	£65,600	£86,400	£107,200	£128,000	£148,800	£169,600	£190,400	£29
16%	0.00482	£188	£283	£377	£471	£565	£660	£754	£848	£39,100	£58,700	£78,200	£97,800	£117,400	£136,900	£156,500	£176,100	£54
17%	0.00508	£173	£267	£361	£455	£548	£642	£736	£830	£34,000	£52,500	£71,000	£89,400	£107,900	£126,300	£144,800	£163,200	£79
18%	0.00535	£158	£251	£345	£438	£531	£625	£718	£812	£29,500	£46,900	£64,400	£81,900	£99,300	£116,800	£134,200	£151,700	£104
19%	0.00562	£142	£235	£328	£421	£514	£607	£700	£793	£25,400	£41,900	£58,500	£75,000	£91,600	£108,100	£124,700	£141,200	£129
20%	0.00588	£127	£220	£312	£405	£497	£590	£682	£775	£21,600	£37,300	£53,100	£68,800	£84,500	£100,300	£116,000	£131,700	£155
21%	0.00615	£112	£204	£296	£388	£480	£572	£665	£757	£18,200	£33,200	£48,100	£63,100	£78,100	£93,100	£108,100	£123,000	£181
22%	0.00642	£96	£188	£280	£372	£463	£555	£647	£739	£15,000	£29,300	£43,600	£57,900	£72,200	£86,500	£100,800	£115,100	£207
23%	0.00668	£81	£172	£264	£355	£446	£538	£629	£720	£12,100	£25,800	£39,500	£53,100	£66,800	£80,400	£94,100	£107,800	£233
24%	0.00695	£66	£157	£248	£338	£429	£520	£611	£702	£9,500	£22,500	£35,600	£48,700	£61,800	£74,800	£87,900	£101,000	£260
25%	0.00722	£50	£141	£231	£322	£412	£503	£593	£684	£7,000	£19,500	£32,100	£44,600	£57,100	£69,700	£82,200	£94,700	£286
26%	0.00748	£35	£125	£215	£305	£395	£485	£575	£665	£4,700	£16,700	£28,800	£40,800	£52,800	£64,900	£76,900	£88,900	£313
27%	0.00775	£20	£109	£199	£289	£378	£468	£558	£647	£2,600	£14,100	£25,700	£37,200	£48,800	£60,400	£71,900	£83,500	£341
28%	0.00802	£5	£94	£183	£272	£361	£451	£540	£629	£600	£11,700	£22,800	£33,900	£45,100	£56,200	£67,300	£78,400	£368
29%	0.00828	-£11	£78	£167	£256	£344	£433	£522	£611	-£1,300	£9,400	£20,100	£30,800	£41,600	£52,300	£63,000	£73,700	£396
vith Proced	dural mortality	v estimate																
5.53%	0.00298	£349	£447	£546	£645	£743	£842	£941	£1.039	£117.200	£150.400	£183.600	£216.700	£249.900	£283.100	£316.200	£349.400	-£165

Table F: All Non-elective Patients, using mean number of stents implanted

Non-Electi	ive Index PC	I	1.467	stent per pa	atient												1	Threshold
Absolute	Incremental			Incrementa	al cost by le	vels of pric	e premium					Incremental	cost per QAL	Y by levels o	of price premi	um		premium
risk	utilty	£100	£200	£300	£400	£500	£600	£700	£800	£100	£200	£300	£400	£500	£600	£700	£800	(£30000)
6%	0.00210	£383	£529	£675	£821	£967	£1,112	£1,258	£1,404	£182,400	£251,700	£321,100	£390,500	£459,800	£529,200	£598,600	£667,900	-£121
8%	0.00262	£351	£496	£641	£786	£931	£1,076	£1,221	£1,366	£134,000	£189,400	£244,700	£300,100	£355,500	£410,800	£466,200	£521,600	-£89
10%	0.00314	£319	£463	£607	£751	£896	£1,040	£1,184	£1,328	£101,600	£147,500	£193,500	£239,500	£285,500	£331,500	£377,500	£423,500	-£56
10.04%	0.00315	£318	£462	£606	£751	£895	£1,039	£1,183	£1,328	£101,100	£146,900	£192,800	£238,600	£284,500	£330,300	£376,200	£422,000	-£56
12%	0.00365	£286	£430	£573	£717	£860	£1,004	£1,147	£1,291	£78,300	£117,600	£156,800	£196,100	£235,400	£274,600	£313,900	£353,200	-£23
14%	0.00417	£254	£396	£539	£682	£825	£967	£1,110	£1,253	£60,800	£95,000	£129,300	£163,500	£197,700	£231,900	£266,100	£300,300	£10
16%	0.00469	£221	£363	£505	£647	£789	£931	£1,073	£1,215	£47,200	£77,500	£107,800	£138,000	£168,300	£198,600	£228,800	£259,100	£44
18%	0.00521	£189	£330	£471	£612	£754	£895	£1,036	£1,177	£36,300	£63,400	£90,500	£117,600	£144,700	£171,900	£199,000	£226,100	£78
20%	0.00572	£157	£297	£437	£578	£718	£859	£999	£1,139	£27,400	£51,900	£76,400	£100,900	£125,500	£150,000	£174,500	£199,000	£112
22%	0.00624	£124	£264	£403	£543	£683	£822	£962	£1,101	£19,900	£42,300	£64,600	£87,000	£109,400	£131,700	£154,100	£176,500	£147
24%	0.00676	£92	£231	£369	£508	£647	£786	£925	£1,064	£13,600	£34,100	£54,700	£75,200	£95,700	£116,300	£136,800	£157,400	£182
26%	0.00728	£59	£197	£335	£474	£612	£750	£888	£1,026	£8,200	£27,100	£46,100	£65,100	£84,100	£103,000	£122,000	£141,000	£217
28%	0.00779	£27	£164	£302	£439	£576	£713	£851	£988	£3,500	£21,100	£38,700	£56,300	£73,900	£91,500	£109,200	£126,800	£253
30%	0.00831	-£5	£131	£268	£404	£541	£677	£814	£950	-£700	£15,800	£32,200	£48,600	£65,000	£81,500	£97,900	£114,300	£289
32%	0.00883	-£38	£98	£234	£369	£505	£641	£777	£912	-£4,300	£11,100	£26,500	£41,800	£57,200	£72,600	£88,000	£103,300	£326
34%	0.00935	-£70	£65	£200	£335	£470	£605	£740	£874	-£7,500	£6,900	£21,400	£35,800	£50,200	£64,700	£79,100	£93,600	£363
36%	0.00986	-£103	£32	£166	£300	£434	£568	£702	£837	-£10,400	£3,200	£16,800	£30,400	£44,000	£57,600	£71,200	£84,800	£401
38%	0.01038	-£135	-£2	£132	£265	£399	£532	£665	£799	-£13,000	-£200	£12,700	£25,500	£38,400	£51,200	£64,100	£77,000	£439
40%	0.01090	-£167	-£35	£98	£230	£363	£496	£628	£761	-£15,400	-£3,200	£9,000	£21,100	£33,300	£45,500	£57,700	£69,800	£477
42%	0.01142	-£200	-£68	£64	£196	£328	£459	£591	£723	-£17,500	-£6,000	£5,600	£17,100	£28,700	£40,200	£51,800	£63,300	£516
44%	0.01193	-£232	-£101	£30	£161	£292	£423	£554	£685	-£19,500	-£8,500	£2,500	£13,500	£24,500	£35,500	£46,400	£57,400	£556
46%	0.01245	-£265	-£134	-£4	£126	£257	£387	£517	£647	-£21,300	-£10,800	-£300	£10,100	£20,600	£31,100	£41,500	£52,000	£596
with Procedural mortality estimate																		
10.04%	0.00523	£318	£462	£606	£751	£895	£1,039	£1,183	£1,328	£60,800	£88,300	£115,900	£143,500	£171,000	£198,600	£226,100	£253,700	-£12

Table G: Non-elective patients receiving a single stent

Non-Electi	ive Index PC	l	1.0	stent per pa	atient													
A b a a b . 4 a . 1	I t - I			l	-1+ 1							l		V b laala a	.			Threshold
	Incremental	0400	0000			vels of price		0700	0000	0400			cost per QAL	-,			2000	premium
risk	utilty	£100	£200	£300	£400	£500	£600	£700	£800	£100	£200	£300	£400	£500	£600	£700	£800	(£30000)
6%	0.00210	£336	£435	£534	£632	£731	£830	£928	£1,027	£160,000	£206,900	£253,800	£300,800	£347,700	£394,700	£441,600	£488,500	-£179
8%	0.00262	£304	£402	£500	£598	£695	£793	£891	£989	£116,000	£153,400	£190,700	£228,100	£265,500	£302,900	£340,200	£377,600	-£131
8.73%	0.00281	£292	£390	£487	£585	£683	£780	£878	£975	£104,000	£138,800	£173,600	£208,300	£243,100	£277,900	£312,600	£347,400	-£114
10%	0.00314	£271	£369	£466	£563	£660	£757	£854	£951	£86,500	£117,500	£148,500	£179,400	£210,400	£241,300	£272,300	£303,300	-£83
12%	0.00365	£239	£335	£432	£528	£624	£721	£817	£913	£65,400	£91,800	£118,100	£144,500	£170,900	£197,200	£223,600	£250,000	-£35
14%	0.00417	£207	£302	£398	£493	£589	£684	£780	£876	£49,500	£72,400	£95,400	£118,300	£141,200	£164,100	£187,000	£209,900	£15
16%	0.00469	£174	£269	£364	£459	£553	£648	£743	£838	£37,200	£57,400	£77,600	£97,800	£118,000	£138,200	£158,500	£178,700	£65
18%	0.00521	£142	£236	£330	£424	£518	£612	£706	£800	£27,200	£45,300	£63,400	£81,400	£99,500	£117,500	£135,600	£153,700	£116
20%	0.00572	£109	£203	£296	£389	£482	£576	£669	£762	£19,100	£35,400	£51,700	£68,000	£84,300	£100,600	£116,900	£133,200	£168
22%	0.00624	£77	£170	£262	£354	£447	£539	£632	£724	£12,300	£27,200	£42,000	£56,800	£71,600	£86,400	£101,200	£116,100	£221
24%	0.00676	£45	£136	£228	£320	£411	£503	£595	£686	£6,600	£20,200	£33,700	£47,300	£60,900	£74,400	£88,000	£101,600	£275
26%	0.00728	£12	£103	£194	£285	£376	£467	£558	£649	£1,700	£14,200	£26,700	£39,200	£51,700	£64,200	£76,700	£89,100	£330
28%	0.00779	-£20	£70	£160	£250	£340	£431	£521	£611	-£2,600	£9,000	£20,500	£32,100	£43,700	£55,200	£66,800	£78,400	£386
30%	0.00831	-£53	£37	£126	£216	£305	£394	£484	£573	-£6,300	£4,400	£15,200	£25,900	£36,700	£47,400	£58,200	£68,900	£442
32%	0.00883	-£85	£4	£92	£181	£269	£358	£447	£535	-£9,600	£400	£10,400	£20,500	£30,500	£40,500	£50,600	£60,600	£500
34%	0.00935	-£117	-£30	£58	£146	£234	£322	£410	£497	-£12,600	-£3,200	£6,200	£15,600	£25,000	£34,400	£43,800	£53,200	£558
36%	0.00986	-£150	-£63	£24	£111	£198	£285	£372	£459	-£15,200	-£6,400	£2,500	£11,300	£20,100	£28,900	£37,800	£46.600	£618
38%	0.01038	-£182	-£96	-£10	£77	£163	£249	£335	£422	-£17.600	-£9,200	-£900	£7,400	£15,700	£24,000	£32,300	£40,600	£679
40%	0.01090	-£215	-£129	-£44	£42	£127	£213	£298	£384	-£19.700	-£11.800	-£4.000	£3.800	£11.700	£19,500	£27,400	£35,200	£741
42%	0.01142	-£247	-£162	-£78	£7	£92	£177	£261	£346	-£21,600	-£14,200	-£6,800	£600	£8,000	£15,500	£22,900	£30,300	£804
44%	0.01193	-£279	-£195	-£112	-£28	£56	£140	£224	£308	-£23,400	-£16,400	-£9,300	-£2,300	£4,700	£11,800	£18,800	£25,800	£868
46%	0.01245	-£312	-£229	-£145	-£62	£21	£104	£187	£270	-£25,000	-£18,400	-£11,700	-£5,000	£1,700	£8,400	£15,000	£21,700	£933
with Proced	dural mortality	estimate /																
8.73%	0.00462	£292	£390	£487	£585	£683	£780	£878	£975	£63,200	£84,300	£105,400	£126,500	£147,700	£168,800	£189,900	£211,000	-£58

NICE SPECIFICATION FOR ADDITIONAL ANALYSIS

Extra analyses (2) for Ischaemic Heart Disease – Coronary Artery Stents– ACD meeting July 2007

Date: March 2007

Project Number	
Appraisal title	Coronary artery stents for the treatment of ischaemic heart disease (part review of NICE technology appraisal guidance no. 71)
Synopsis of the technical issue	Following the recent concerns over the issue of safety of drug-eluting stents (DES) and the recent conclusions of the FDA advisory panel, views have been expressed that the duration of use of anti-platelet therapy (aspirin and clopidogrel) should be extended in patients who have received a DES to 12 months, and in particular in those patients whose lesions are thought to be high risk. As a result of this, further work is requested to be undertaken to examine how the difference in the duration of clopidogrel use between bare-metal stents (BMS) and DES may affect the cost effectiveness.



Question(s) to be answered by the	What is the cost effectiveness of DES in the treatment of ischaemic heart disease, given that
Assessment Group	there is a difference in the duration of clopidogrel between patients receiving a DES and
	those receiving a BMS.
	 The base-case scenario should incorporate the cost (using BNF acquisition costs) of clopidogrel in BMS patients (3 months) and the cost of clopidogrel for DES patients (12 months)
	 Sensitivity analysis should be carried out around the number of stents used, for both the average number of stents and one stent only for both scenarios.
How will these questions be addressed	The Assessment Group will be asked to:
in an addendum?	re-run the model, containing these costs
	re-run the sensitivity analysis
	 present the analyses for the same range of absolute rates of revascularisation of BMS for mean number of stents and one stent only, for elective and non- elective patients as seen in tables B, C, F and G and include a copy of table A from addendum 3" (2006).
Date for delivery of report to Institute	10 th April 2007

