TECHNOLOGY ASSESSMENT REPORT FOR THE HTA PROGRAMME
FINAL VERSION: 21 March 2005

TAR Title:
Drug-eluting stents (update to Guidance Number 71)

Appraisal title:
Coronary artery stents for the prevention of ischaemic heart disease (update to Guidance Number 71)

A. Details of appraisal group

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B. Full title of research question

To provide an updated assessment for review of National Institute for Clinical Excellence (NICE) Guidance 71.

The technology assessment report (TAR) will consider people with coronary artery disease (CAD), who are suitable for treatment by percutaneous coronary intervention (PCI) with the use of stent(s). The TAR will assess the clinical and cost effectiveness of drug-eluting stents for the prevention of restenosis following PCI. Drug-eluting stents (DES) will be compared with non drug-eluting stents and a comparison between DES designs will be presented if data allow.

New DES: drug-eluting stents not included in the previous assessment, which have since been developed for market and expected to receive CE Marking before 30 September 2005. The Cypher Select™ and Taxus® Liberte™ DES could be regarded as 'modified' designs of existing DES systems, but equivalence with existing DES will not be assumed.

Existing DES: drug-eluting stents previously considered for appraisal, already with CE Marking and commercially available; namely, *Cypher*™ (Cordis Inc.); *Taxus*™ (Boston Scientific Corp.) and *Dexamet*™ (Abbott Labs.).

C. Clarification of research question and scope

Clinical comparisons
In patient populations with CAD, suitable for treatment with PCI with the use of stent(s), comparison will be made between:

- Drug-eluting stent and non DES (such as comparator bare metal stents)
- DES of different design (i.e. DES versus DES).

If evidence allows, clinical effects of DES in subgroups of patients will be explored (see *Participants*, Appendix I).

Economic evaluation
New data on existing DES evaluated in the previous appraisal (*Cypher, Taxus*) will be incorporated into our economic model (see later in Part D).

The evaluation of economic evidence will include quality assessment of published cost minimisation, cost effectiveness, cost utility and cost benefit analyses of new and existing DES. Economic models included in the manufacturer submissions will be critiqued as appropriate.

If appropriate data are available, an economic model will be developed to estimate the cost effectiveness of:

- DES compared to non DES
- DES compared with other DES.

Due to the very recent introduction of new DES designs, economic evaluation will be heavily dependant on the timing, quality and level of data provided by the manufacturers.

D. Report Methods

The National Institute for Clinical Excellence (NICE) issued updated Guidance (Number 71) on the use of coronary artery stents in October 2003.(1) The TAR, which was produced to inform the Guidance, was published as part of the Health Technology Assessment (HTA) monograph series in 2004.(2)

Clearly, the proposed assessment described in this protocol has a relationship to the current Guidance(1) and previously conducted research(2) which informed its development. Methodologies and findings of the earlier HTA will likely be referred to throughout the proposed review.

Search strategy
The following databases will be searched for relevant published literature for the period from December 2002 to June 2005. Searching will date from the limit of the search in the previous assessment.(2)

- CDSR (Cochrane Database of Systematic Reviews)
- CENTRAL (Cochrane Central Register of Controlled Trials)
- DARE (Database of Abstracts of Reviews of Effectiveness)
- EMBASE
- HTA database
- ISI Web of Science- Proceedings (Index to Scientific & Technical Proceedings)
- ISI Web of Science- Science Citation Index Expanded
- MEDLINE (using the PubMed interface for last 3 months of searching)
- NHS EED (NHS Economic Evaluation Database)

Research groups identified through searches will be contacted for information about ongoing trials.

The information sources below will be examined for information on studies. If data are available, these will be considered for inclusion in the assessment.

- BIOSIS (http://edina.ac.uk/biosis/)
- Cardiovascular Revascularization Therapies (www.crtonline.com)
- ClinicalTrials.gov – National Institutes of Health database (http://www.clinicaltrials.gov)
- The heart.org (www.theheart.org)
- Transcatheter Cardiovascular Therapeutics (www.tctmd.com)
- Trends in Medicine (http://www.trends-in-medicine.com)

As an experiment, the *Google Scholar* Internet search engine will be used for searching for information on studies and background information. Also the *TRIP Database plus* will be evaluated for its usefulness in our searching activities. Results of these searches may not necessarily be included in the TAR.

- Google Scholar http://www.scholar.google.com/advanced_scholar_search)
- TRIP Database plus (http://www.tripdatabase.com)

Bibliographies of reviews, retrieved articles and submissions to the NICE will be searched for further studies.

Handsearching of cardiology conference abstracts will be conducted (online, where this facility is available). Specifically, recent conference proceedings for the following meetings will be obtained for the purposes of handsearching:

- American College of Cardiology
- American Heart Association
- British Cardiac Society
- European Society of Cardiology
- Transcatheter Cardiovascular Therapeutics

Handsearching of recent issues of journals that might not yet have been indexed in electronic databases covering the period from March 2005 to June 2005 will be conducted. Internet resources (including industry supported WebPages) will be examined for information on clinical trials and cost data.

Full details of the search strategies used and process of selection of evidence sources will be recorded.

Inclusion and exclusion criteria

a. Inclusion criteria

Study designs	**Clinical effectiveness:** Primarily: RCTs, systematic reviews Secondly: Non-RCTs, including case control or uncontrolled study designs In our approach to data analysis, a hierarchy of evidence will be applied, where data from RCTs will be used in preference to data from other types of investigation **Economic evaluation:** Full economic evaluations that consider both costs and consequences (cost-effectiveness, cost-utility, cost-minimisation and cost-benefit analyses)
Patient population	Adults with CAD, undergoing treatment of native and intervention naïve vessel(s) by PCI with the use of stent(s)
Interventions/ Comparators	• Drug-eluting stent versus non DES • DES of different design (i.e. DES versus DES)
Outcomes	**Clinical:** • Combined event rate (major adverse cardiac events - MACE, target vessel failure - TVF) or event free survival • Mortality (all cause, cardiac) • Acute Myocardial Infarction (AMI) • Target Lesion Revascularisation (TLR) • Target Vessel Revascularisation (TVR) • Repeat revascularisation (PCI/stent, other PCI or CABG) • Adverse effects (thrombosis, mal-absorption; incomplete stent apposition; device failures/defects) **Angiographic:** • Angiographic binary restenosis • Late loss **Health related quality of life.** **Economic:** • Incremental cost per QALY

b. Exclusion criteria

RCTs that:
- provide only unplanned, interim findings
- provide data on only a sub-group of the enrolled patients
- are continuing to recruit patients
- where patients numbers treated with specific intervention (i.e. a particular type of stent) can not be determined.

Studies on:
- treatment of in-stent restenosis
- treatment of saphenous vein grafts.

Comparison of:
- DES with other PCI interventions (e.g. Atherectomy, Rotabaltors, Brachytherapy)
- DES with surgery
- variations of drug-loading among single DES types (brands).

Quality assessment strategy
All included studies, resulting from our searching, will be assessed for methodological quality. The quality of clinical effectiveness studies will be assessed using criteria based on CRD Report No. 4.(3)

Cost effectiveness studies will be quality assessed using criteria from the 35 item checklist developed by Drummond and Jefferson.(4)

Two reviewers will independently evaluate the quality of the included studies and discuss disagreements where necessary. A third reviewer will be consulted, if necessary, to achieve consensus.

Data extraction strategy
Data from sources located in our search will be extracted as detailed below and will include information listed in Appendix I.

Data relating to study design, findings and quality will be extracted by one reviewer and independently checked for accuracy by a second reviewer. Study details will be extracted on pre-tested data extraction forms. Time permitting; authors (and sponsors) of the studies will be contacted for missing data. Data from studies presented in multiple publications will be extracted and reported as a single study with all other relevant publications listed.

Methods of analysis/synthesis

a. Methods of analysis for clinical studies
Individual study data and quality assessment will be summarised in structured tables and as a narrative description. Potential effects of study quality will be discussed.

For binary outcomes, where sufficient data are available, relative treatment effects will be presented in the form of relative risks (RR). For continuous outcomes, mean differences will be calculated. For time to event outcomes, hazard ratios (HR) will be presented. Data will be pooled only if this makes sense clinically and statistically. If estimates of log HR and its variance are not quoted directly in trial reports and Individual Patient Data (IPD) are unavailable, alternative aggregate data (e.g., log rank test p-value) will be extracted in order to calculate pooled HR estimates.(5) Heterogeneity between studies will be assessed by considering differences in the (a) study population, (b) intervention, (c) outcome measures and (d) study quality.

b. Methods of analysis for economic studies

Individual study data and quality assessment will be summarised in structured tables and as a narrative description. Potential effects of study quality will be discussed.

To supplement findings from the economic literature review, additional cost and benefit information from other sources, including the industry submissions to NICE, will be collated and presented as appropriate.

Methods for estimating quality of life, costs and cost-effectiveness and/or cost/QALY

a. Modelling

Industry submitted models

We will conduct a review of any industry submitted model(s). Reviews will include a summary description of the model and a critical appraisal of key structures, assumptions, resources, data and sensitivity analysis. In addition, we will provide an assessment of the model's strengths and weaknesses and discuss the implications of using different assumptions in the model.

Assessment Group model

Our ability to construct an economic model will depend on the data available. It is anticipated that a model will be developed to estimate the comparative cost-effectiveness of alternative treatment strategies, specifically comparing two key areas of the current review:

- Drug-eluting stents and non DES
- DES compared with other DES

The results will be presented in terms of cost per quality adjusted life year gained (QALY), using appropriate utility data. If sufficient utility data are not available to construct QALYs with substantial precision, incremental cost effectiveness analysis or cost minimisation analysis will be undertaken. This model will combine clinical and cost-effectiveness data from the systematic review and expert clinical opinion (e.g. advisory panel members, clinicians undertaking stenting); cost data relevant to the UK NHS will also be incorporated. Further details of cost and benefit data requirements are summarised in the next section.

Should suitable individual patient data (IPD) be made available and depending on the character of any IPD supplied, the nature of any variation in resource use and clinical outcomes may be explored in the modelling exercise.

In the previous assessment of DES(2) the dominant influences on cost effectiveness were the proportion of patients with recurrent symptoms necessitating an early repeat revascularisation (within 6 to 8 months of index procedure, but certainly within 12 months), and the incremental cost of DES compared to bare metal stents made up of the differential price per stent and the number of DES used. Our presentation of cost-effectiveness results, in the forthcoming assessment, will be structured to reflect the importance of these factors.

Within the presentation of reference case results, we will provide an analysis showing the main factors contributing to any differences in cost effectiveness results between the industry submissions and ourselves.

Exploratory assessment: clinical management of the targeted use of DES

The Assessment Group have been advised that for some PCI centres a mix of DES and non DES may be used for revascularisation of an individual. If it was possible for the cardiologist to accurately pinpoint the lesion most likely to require re-intervention and target use of DES to this lesion, then the patient could expect to gain most of the benefit from multiple DES, but by only a using a single DES alongside less costly non DES. Since cost-effectiveness ratios are largely determined by the high

extra cost of DES compared to existing non DES, the ability to limit the use of DES to one per patient may substantially improve cost-effectiveness for several patient sub-groups.

Ideally, if suitable data were available and could be analysed, health services researchers working with cardiologists might wish to develop clinical management tools to assist in identifying lesions where the use of DES may be expected to have critical influence of outcomes and cost-effectiveness. Development of such a tool is not a primary objective for this TAR, but following our discussions with clinical experts, PCI centres and in our literature searching, we intend to outline the availability of information on mixed stent use in PCI.

b. Cost data

The primary perspective for the analysis of cost information will be the NHS and personal social services (PSS). Cost data will therefore focus on the marginal direct health service costs associated with device and interventions.

Quantities of resources used will be identified from consultation with experts, primary data from relevant sources and the reviewed literature. Unit cost data will be extracted from the literature (e.g. Personal Social Services Research Unit) or obtained from other relevant sources (drug price lists, NHS reference costs and Chartered Institute of Public Finance and Accounting cost databases). All cost data will be converted to a single year (2004) in pounds sterling.

Where appropriate costs will be discounted at 6.0% per annum, the rate recommended in NICE guidance to manufacturers and sponsors of submissions. Sensitivity analyses will be performed to explore the effects of varying the discounting rate to 3.5%.

c. Assessment of benefits

A balance sheet will be constructed to list benefits and costs arising from alternative treatment options. We anticipate that the main measures of benefit will be QALY gained.

Where appropriate, effectiveness and other measures of benefit will be discounted at 1.5%, the rate recommended in NICE guidance to manufacturers and sponsors of submissions. Sensitivity analyses will be performed to explore the effects of varying the discounting rate to 3.5%.

d. Sensitivity Analysis

If appropriate, sensitivity analysis will be applied to our model in order to assess the robustness of the results to realistic variations in the levels of the underlying data (e.g. acquisition price of devices). Where the overall results are sensitive to a particular variable, the sensitivity analysis will analyse the exact nature of the impact of variations.

Imprecision in the principal model cost-effectiveness results with respect to key parameter values will be assessed by use of techniques compatible with the modelling methodology deemed appropriate to the research question and to the potential impact on decision-making for specific comparisons (e.g. multi-way sensitivity analysis, cost-effectiveness acceptability curves etc).

The results of the evaluation will be used to estimate comparative cost-utility/effectiveness ratios under different treatment scenarios based upon appropriate subgroups of patients.

E. Handling the company submission(s)

The Liverpool Reviews and Implementation Group intends to use the industry dossier:

- As a source of data, looking for studies that meet the inclusion criteria (RCTs/other studies of effectiveness as well as cost-effectiveness, cost utility studies and cost benefit analysis).
- To undertake a critique of any industry models, including the strengths and weaknesses and the implications of different assumptions. The detail to which this can be undertaken will depend

on the number and size of company dossiers submitted. Clarification of particular aspects of the model may be sought from the manufacturer.

Any 'commercial in confidence' or 'academic in confidence' data taken from the submission(s) or other sources will be underlined in our report (followed with an indication of the source of the data in parenthesis).

F. Project Management

a Timetable/milestones:

Submission	Date [Estimate]
Draft protocol	07 Mar 2005 (submitted 04 Mar 2005)
Finalised protocol	21 Mar 2005
Consultee submissions to AG	08 Jun 2005
Progress report	15 June 2005
Complete, near final draft report to external reviewers and NICE Technical Lead	[03 Aug 2005]
Final assessment report to NICE	12 September 2005

b. Review Advisory Panel

The Group will recruit an *Advisory Panel* of experts to support the development of the review. Panel members may advise on specific sections of the review: clinical, healthcare policy, health economics, statistics and review methodology.

c. External Referees

The Technology Assessment Report will be subject to external peer review by at least two clinical experts and one methodological expert. These *referees* will be chosen according to academic seniority and content expertise and will be agreed with NCCHTA. External expert referees will see a complete and near final draft of the TAR and will understand that their role is part of external quality assurance. All referees are required to sign a copy of the NICE Confidentiality Acknowledgement and Undertaking. We will send external referees' signed copies to NCCHTA. Comments from the referees and the Technical Lead at NICE, together with our responses to these will be made available to NCCHTA in strict confidence for editorial review and approval.

d. Competing Interests

No competing interests exist for members of the Assessment Group. Any competing interests relating to the external reviewers will be declared in the final report.

G. Appendices

I Details of data extraction

Clinical effectiveness data to be extracted will include, but not be limited to:

Study Details:

- Study bibliographic data
- Type of report (abstract, full manuscript, interim report)
- Type of study
- Methodological details of study
- Concomitant therapies
- Details of funding.

Participants:

- Age
- Sex
- Disease status (including vessel and lesion characteristics such as vessel diameter, lesion length, complex lesions, partial or total occlusion)
- Diabetes
- AMI
- Number recruited or accrued
- Length of follow-up
- Nature of follow-up (angiographic and clinically driven or clinically driven only).

Results (data for all outcomes specified will be extracted as available):

- Combined event rate (such as major adverse cardiac event - MACE, target vessel failure - TVF) or event free survival[1]
- Mortality (short term and long term; all cause and cardiac)
- AMI
- Target Lesion Revascularisation (TLR)
- Target Vessel Revascularisation (TVR
- Repeat revascularisation (PTCA, stent or CABG)
- Angiographic binary restenosis rate i.e. re-narrowing of treated vessel by 50% or more, when assessed by angiography (BRR)
- Late loss
- Health related quality of life
- Adverse effects (in addition to those events recorded in MACE, such as: thrombosis, mal-absorption; incomplete stent apposition; device failures/defects).

[1] Care will be taken to determine the composition and comparability of combined event rates. We note that some combined event rates differ in their inclusion of, for example, all cause or only cardiac deaths or TVR or TLR

Cost effectiveness data extraction will include, but not be limited to:

Study characteristics:
- Type of evaluation and synthesis
- Intervention
- Study population
- Time period of study.

Cost data and cost data sources:
- Cost items
- Cost data sources
- Country, currency year.

Outcome data and data sources:
- Range of outcomes
- Efficiency data sources
- Modelling method and data sources
- Probabilities and assumptions of models.

Cost effectiveness:
- Cost effectiveness ratios
- Subgroup analysis and results
- Sensitivity analysis and results
- Authors' conclusions.

II Details of quality assessment

a. **Studies of clinical effectiveness**

RCTs will be assessed using the following criteria, based on CRD Report No. 4(3)

- Was the method used to assign participants to the treatment groups really random? *(Computer generated random numbers and random number tables will be accepted as adequate, whilst inadequate approaches will include the use of alternation, case record numbers, birth dates or days of the week)*
- Was the allocation of treatment concealed? *(Concealment will be deemed adequate where randomisation is centralised or pharmacy-controlled, or where the following are used: serially numbered containers, on-site computer-based systems where assignment is unreadable until after allocation, other methods with robust methods to prevent foreknowledge of the allocation sequence to clinicians and patients. Inadequate approaches will include: the use of alternation, case record numbers, days of the week, open random number lists and serially numbered envelopes even if opaque)*
- Was the number of participants who were randomised stated?
- Were details of baseline comparability presented in terms of treatment free interval, disease bulk, number of previous regimens, age, histology and performance status?
- Was baseline comparability achieved for treatment free interval, disease bulk, number of previous regimens, age, histology and performance status?
- Were the eligibility criteria for study entry specified?
- Were any co-interventions identified that may influence the outcomes for each group?
- Were the outcome assessors blinded to the treatment allocation?
- Were the individuals who were administered the intervention blinded to the treatment allocation?
- Were the participants who received the intervention blinded to the treatment allocation?
- Was the success of the blinding procedure assessed?
- Were at least 80% of the participants originally included in the randomisation process, followed up in the final analysis?
- Were the reasons for any withdrawals stated?
- Was an intention to treat analysis included?

Items will be graded in terms of ✓ **yes** (item adequately addressed), ✗ **no** (item not adequately addressed), ✓/✗ *partially* (item partially addressed), **?** **unclear** or not enough information, **NA** not applicable or **NS** not stated.

Non-RCTs will be assessed using criteria for assessing case series outlined in CRD Report No. 4(3) Below are listed '**Some quality criteria for assessment of observational studies'** taken from Box 5.9, CRD Report 4.

- Is the study based on a representative sample selected from a relevant population?
- Are the criteria for inclusion explicit?
- Did all individuals enter the survey at a similar point in their disease progression?
- Was follow-up long enough for important events to occur?
- Were outcomes assessed using objective criteria or was blinding used?
- If comparisons of sub-series are being made, was there sufficient description of the series and the distribution of prognostic factors?

Items will be graded in terms of ✓ **yes** (item adequately addressed), ✗ **no** (item not adequately addressed), ✓/✗ *partially* (item partially addressed), **?** **unclear** or not enough information, **NA** not applicable or **NS** not stated.

b. Studies of cost effectiveness will be assessed using the following criteria, which is an updated version of the checklist developed by Drummond and Jefferson.(4)

Study design:

- The research question is stated
- The economic importance of the research question is stated
- The viewpoint(s) of the analysis are clearly stated and justified
- The rationale for choosing the alternative programmes or interventions compared is stated
- The alternatives being compared are clearly described
- The form of economic evaluation used is stated
- The choice of form of economic evaluation is justified in relation to the questions addressed.

Data collection:

- The source(s) of effectiveness estimates used are stated
- Details of the design and results of effectiveness study are given (if based on a single study)
- Details of the method of synthesis or meta-analysis of estimates are given (if based on an overview of a number of effectiveness studies)
- The primary outcome measure(s) for the economic evaluation are clearly stated
- Methods to value health states and other benefits are stated
- Details of the subjects from whom valuations were obtained are given
- Productivity changes (if included) are reported separately
- The relevance of productivity changes to the study question is discussed
- Quantities of resources are reported separately from their unit costs
- Methods for the estimation of quantities and unit costs are described
- Currency and price data are recorded
- Details of currency of price adjustments for inflation or currency conversion are given
- Details of any model used are given
- The choice of model used and the key parameters on which it is based are justified.

Analysis and interpretation of results:

- Time horizon of costs and benefits is stated
- The discount rate(s) is stated
- The choice of rate(s) is justified
- An explanation is given if costs or benefits are not discounted
- Details of statistical tests and confidence intervals are given for stochastic data

- The approach to sensitivity analysis is given
- The choice of variables for sensitivity analysis is justified
- The ranges over which the variables are varied are stated
- Relevant alternatives are compared
- Incremental analysis is reported
- Major outcomes are presented in a disaggregated as well as aggregated form
- The answer to the study question is given
- Conclusions follow from the data reported
- Conclusions are accompanied by the appropriate caveats.

All items will be graded as either ✓ **yes** (item adequately addressed), ✗ no (item not adequately addressed), **?** **unclear** or not enough information, **NA** not appropriate or **NS** not stated.

III. Background

Coronary artery disease (CAD) is a major cause of morbidity and mortality in the UK accounting for more than 100,000 deaths per year in England and Wales. Build-up of material, forming plaques, result in a narrowing (occlusion) of the blood vessels supplying the heart muscle. This in turn results in reduced blood flow and thus supply of oxygen to the heart muscle. Plaques can be unstable and cause symptoms of 'unstable angina', although some people may not experience noticeable signs of CAD. Complete blockage of arteries results in acute myocardial infarction (heart attack) which risks life and lasting damage to the heart.

Risk factors for CAD include smoking, poor diet and lack of exercise. Primary prevention, involving changes in these behaviours may influence the risk of developing CAD. Treatments for CAD and its symptoms include modification of risk factors, such as those for primary prevention, and medication. Where these measures are insufficient, more invasive therapies may be employed. These include surgery to replace occluded arteries, or percutaneous coronary interventions (PCI) to clear or reduce narrowing within vessels.

The technology

In PCI, a small elongated balloon is introduced into a patient's artery (without the need for surgery) and inflated once located at the site of the plaque (lesion), effectively compacting the deposited material against the vessel wall. This procedure, termed percutaneous transluminal coronary angioplasty (PTCA) has been commonly used since the 1980s. Although successful in expanding vessel diameter, PTCA suffered from two major drawbacks – acute closure of the vessel during the procedure treatment and restenosis (re-narrowing) of the vessel following treatment. In an adaptation to PTCA 'alone', tiny metallic mesh tubes (stents) can also be guided to the site of the lesion and scaffold the vessel open. Percutaneous coronary intervention with the use of stents reduces procedural complications and restenosis (re-narrowing) of treated vessels. Procedural success rates for deploying these stents are high, complication rates are low and most patients experience improvement in symptoms after the intervention. However, a proportion of patients still experience restenosis following treatment with PCI using stents. Other patients, due to the extent of their CAD, are not suitable for treatment by PCI.

Further modification of PCI technology involves the use of stents that release an antiproliferative agent into the area surround the stents. The agent released from these drug-eluting stents (DES) act to reduce cell migration and growth at the site of the stent and thereby reduce the risk of restenosis, without the toxicity associated with the patient taking a drug which acts systemically.(6)

Current service provision

The British Cardiovascular Intervention Society (BCIS) provide annual audit data related to the use of PCI in the UK.(7)

Provision of PCI in the UK in 2002 was reported to be 759 per million (44, 913 procedures) rising to 894 per million (53, 261 procedures) for 2003. This level of provision exceeds rates in some other European countries (e.g. Spain, Denmark, Finland and Greece) but is much lower than countries such as France, Switzerland, Belgium and Germany where the reported rates in 1998 were greater than 1200 per million.(2)

BCIS Audit data for 2003(7) suggest that DES were being used in 18.3% of cases in England (28.6% in Wales) - data from 64 of 73 centres in the UK.

Economics

This new technology comes at a considerable additional cost (typically £1300 to 1500 for DES compared to £600 to 900 for non DES), but this additional cost may be offset by the value to the patient of avoidance of symptoms of CAD and a reduction in the need for reintervention to treat restenosis.

The NHS need to consider clinical and cost effectiveness of this technology. Accordingly, the use of coronary artery stents has been previously appraised by NICE in 2000(8) and 2003.(1) These devices are evolving rapidly in their design. NICE have responded by initiating a further appraisal of drug-eluting stents (DES) to include longer term follow-up of established DES and new, emerging DES designs (see table below).

DES anticipated to be included in the TAR

Existing DES:		*Manufacturer:*	*CE Marking:*	*Previous Assmnt:*
1.	*Cypher™*	Cordis	✓	✓
2.	*Taxus™*	Boston Scientific	✓	✓
3.	*Dexamet™*	Abbott/Biocompatibles	✓	×
New DES:		*Manufacturer:*	*CE Marking:*	*Previous Assmnt:*
4.	*Costar™.*	Biotronik/Conor	*Pending*	×
5.	*Cypher Select™*	Cordis	✓	×
6.	*Endeavor™*	Medtronic	*Pending*	×
7.	*Janis™*	Sorin	✓	×
8.	*Liberte™*	Boston Scientific	*Pending*	×
9.	*Xience V™*	Guidant	*Pending*	×
10.	*Yukon™*	Kiwimed/Translumina	✓	×

Adapted from: Coronary artery stents for the treatment of ischaemic heart disease (Update to guidance No. 71) Final Scope, Appendix A-1 [File: signed off 16 02 05 FINAL.doc]

IV References

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8. National Institute for Clinical Excellence. Guidance on coronary artery stents in the treatment of ischaemic heart disease (Technology Appraisal Guidance no.4). London: National Institute for Clinical Excellence; 2000