NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

GUIDANCE EXECUTIVE (GE)

Consideration of consultation responses on review proposal

Review of TA236; Ticagrelor for treating acute coronary syndromes

This guidance was issued October 2011 with a review date of March 2013.

Background

At the GE meeting of 5 March 2013 it was agreed we would consult on the review plans for this guidance. A four week consultation has been conducted with consultees and commentators and the responses are presented below.

Proposal put to consultees:	The guidance should be transferred to the 'static guidance list' and incorporated into the forthcoming NICE clinical guideline on the management of myocardial infarction with ST-segment elevation. That we consult on this proposal.
Rationale for selecting this proposal	The evidence base for ticagrelor has not changed significantly since publication of TA 236. The price of the comparator, clopidogrel, is now 25% lower than it was in TA236. However, because the ICERs in TA236 were at the lower end of what is normally considered cost effective (£7897 per QALY gained for all ACS, £8872 per QALY gained for STEMI, £7215 per QALY gained for NSTEMI and £9131 per QALY gained for unstable angina), it is not expected that the slightly lower comparator price would lead to the need to change the recommendations. The update of TA182 (prasugrel for ACS) are not expected to affect the recommendation for ticagrelor, as the latter did not depend on a comparison with prasugrel.

GE is asked to consider the original proposal in the light of the comments received from consultees and commentators, together with any responses from the appraisal team. It is asked to agree on the final course of action for the review.

Recommendation post consultation:	The guidance should be transferred to the 'static guidance list' and incorporated into the forthcoming NICE clinical guideline on the management of myocardial infarction with ST-segment elevation.

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Cochrane Heart Group	No comment	Unfortunately we do not have any authors working on a Cochrane Heart Review on the topic area.	Comment noted. No action required
Medicines and Healthcare Products Regulatory Agency	Agree	We don't know of any evidence that might impinge on your proposal.	Comment noted. No action required
British Cardiovascular Society	Agree	We are not aware of any new evidence that would suggest a NICE review beneficial and change its recommendations.	Comment noted. No action required.
Royal College of Physicians	Agree	The RCP wishes to endorse the comments submitted by the BCS.	Comment noted. No action required
AstraZeneca	Agree	**Section 1** Currently there is no mention of incorporation of TA236 into future Unstable Angina (UA) and non-ST-segment-elevation myocardial infarction (NSTEMI) Clinical Guidelines (CG94). We	The review decision of clinical guideline 94 was to not update this guideline at this time (October 2012). However, it was stated that the guideline should be amended to cross refer to the technology appraisal 236

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		therefore seek clarity as to how NICE will incorporate TAG236 into CG94. **Section 3 and Section 7** We would recommend to NICE to include a definition of "option" in TAG236 when it is moved into the static list for this will provide greater clarity to readers of the GE and TA236. The definition we have been sent by NICE is as follows - *The technology in this appraisal may not be the only treatment for acute coronary syndromes recommended in NICE guidance, or otherwise available in the NHS. Therefore, if a NICE technology appraisal recommends use of a technology, it is as an option for the treatment of a disease or condition. This means that the technology should be available for a patient who meets the clinical criteria set out in the guidance, subject to the clinical judgement of the treating clinician. The NHS must provide funding and resources (in line with section xxx) when the clinician concludes and the patient agrees that the recommended technology is the most appropriate to use, based on a discussion of all available treatments.* Please find below a list of trials that were not listed in GE proposal paper that we believe to be relevant to the Technology Appraisal:	(ticagrelor for the treatment of acute coronary syndromes) that was previously not mentioned in guideline 94. Comment noted. The publishing team is exploring the resources needed for this activity. Comment noted. Literature searches are carried out every 5 years to check whether any of the Appraisals on the static list should

Respondent	Response to proposal	Details	Comment from Technology Appraisals
		• GLOBAL LEADERS: A Clinical Study Comparing Two Forms of Anti-platelet Therapy After Stent Implantation (NCT01813435) Estimated enrollment = 16,000 Estimated study completion date = June 2016 • A Post Marketing Surveillance to Evaluate the Safety and Efficacy of Brilinta (NCT01611272) Estimated enrollment = 3500 Estimated study completion date = December 2016 • Comparison of Ticagrelor Versus Clopidogrel on Residual Thrombus Burden During PCI: an OCT Study (NCT01826175) Estimated enrollment = 300 Estimated study completion date = August 2012 • Ticagrelor and Aspirin for the Prevention of Cardiovascular Events After Coronary Artery Bypass Surgery (TAP-CABG) (NCT01373411) Estimated enrollment = 244 Estimated study completion date = December 2014	be identified for review by the Guidance Executive. NICE will consider all the relevant evidence in its decision. See section 6 'Guide to the single technology appraisal process' Comment noted. The updated estimated study completion date for this clinical trial is August 2014

Respondent	Response to proposal	Details	Comment from Technology Appraisals
		• Endothelium, Stenting, and Antiplatelet Therapy (EST) - Clopidogrel, Prasugrel, Ticagrelor Study (NCT01700322) Estimated enrollment = 78 Estimated study completion date = August 2015 • Platelet Activation, Reactivity, and Inflammation After Coronary Bypass Surgery In Patients Treated With Ticagrelor or Clopidogrel (NCT01793597) Estimated enrollment = 50 Estimated study completion date = March 2014	
Royal College of Nursing	No comment	Feedback received from nurses working in this area of health suggest that there is no additional evidence to submit on behalf of the Royal College of Nursing to inform on the review proposal of the development of this guidance, other than what can be found in systematic reviews.	Comment noted. No action required

No response received from:

Patient/carer groups	General
• Action Heart	• Allied Health Professionals Federation

- Afiya Trust
- Black Health Agency
- Blood Pressure UK
- British Cardiac Patients Association
- Cardiac Risk in the Young
- Coronary Prevention Group
- Equalities National Council
- Heart Care Partnership
- HEART UK
- Independent Age
- Muslim Council of Britain
- Muslim Health Network
- Network of Sikh Organisations
- South Asian Health Foundation
- Specialised Healthcare Alliance
- The Somerville Foundation (formerly known as Grown Up Congenital Heart Patients Association)

<u>Professional groups</u>

- British Association for Nursing in Cardiovascular Care
- British Association for Services to the Elderly
- British Atherosclerosis Society
- British Cardiovascular Intervention Society
- British Geriatrics Society
- British Heart Foundation
- British Nuclear Cardiology Society
- British Society For Heart Failure
- British Society of Cardiovascular Imaging
- College of Emergency Medicine
- National Heart Forum
- Board of Community Health Councils in Wales
- British National Formulary
- Care Quality Commission
- Commissioning Support Appraisals Service
- Department of Health, Social Services and Public Safety for Northern Ireland
- Healthcare Improvement Scotland
- National Association of Primary Care
- National Pharmacy Association
- NHS Alliance
- NHS Commercial Medicines Unit
- NHS Confederation
- Public Health Wales NHS Trust
- Scottish Medicines Consortium

<u>Comparator manufacturers</u>

- Actavis UK (clopidogrel)
- Arrow Generics (clopidogrel)
- Aspire Pharma (clopidogrel)
- Beacon Pharmaceuticals (clopidogrel)
- Daiichi Sankyo (prasugrel)
- Dexcel-Pharma (clopidogrel)
- Dr Reddy's Laboratories (clopidogrel)
- Lilly UK (prasugrel)
- Sandoz (clopidogrel)
- Sanofi (clopidogrel)
- Teva UK (clopidogrel)
- Wockhardt UK (clopidogrel)

<u>Relevant research groups</u>

• Primary Care Cardiovascular Society • Royal College of General Practitioners • Royal College of Pathologists • Royal Pharmaceutical Society • Royal Society of Medicine • Society for Cardiological Science and Technology • United Kingdom Clinical Pharmacy Association • Vascular Society of Great Britain and Ireland <u>Others</u> • Cambridgeshire and Peterborough PCT Cluster • Department of Health • Hertfordshire PCT Cluster • Welsh Government	• Antithrombotic Trialists' (ATT) Collaboration • British Society for Cardiovascular Research [BCS affiliated] • Cardiac and Cardiology Research Dept, Barts • Central Cardiac Audit Database • Cochrane Hypertension Group • Cochrane Peripheral Vascular Diseases Group • Cochrane Stroke Group • CORDA • European Council for Cardiovascular Research • Health Research Authority • MRC Clinical Trials Unit • National Heart Research Fund • National Institute for Health Research • Research Institute for the Care of Older People • Wellcome Trust <u>Assessment Group</u> • Assessment Group tbc • National Institute for Health Research Health Technology Assessment Programme <u>Associated Guideline Groups</u> • National Clinical Guidelines Centre <u>Associated Public Health Groups</u> • None

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