

**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

**GUIDANCE EXECUTIVE (GE)**

**Consideration of consultation responses on review proposal**

**Review of TA210; Clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events (review of Technology Appraisal No. 90)**

This guidance was issued December 2010 with a review date of July 2013.

**Background**

At the GE meeting of 16 July 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.

<b>Proposal put to consultees:</b>	The guidance should be transferred to the 'static guidance list'.
<b>Rationale for selecting this proposal</b>	There is little new evidence for the treatments as specified in the recommendations and that which there is agrees with the evidence submitted as part of the TA210 appraisal. The new evidence identified will not lead to a change in the recommendations of the original guidance.

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.

<b>Recommendation post consultation:</b>	The guidance should be transferred to the 'static guidance list'.
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Respondent	Response to proposal	Details	Comment from Technology Appraisals
British Association of Stroke Physicians (BASP)	Agree	BASP agrees with NICE that there is no additional evidence relevant to this particular technology appraisal. However, there are recently completed and ongoing randomised trials of antiplatelet regimens for the prevention of vascular occlusive events following an ischaemic stroke or TIA that may impact on the most appropriate choice of antiplatelet regimen for these patients. These trials include the recently published Chinese CHANCE trial (New Engl J Med 2013) and the ongoing POINT and TARDIS trials. BASP believes that incorporation of the results of these and other relevant trials into guidance from NICE on antiplatelet treatment after ischaemic stroke or TIA would be appropriate.	<p>Comments noted. An update of <a href="#">Clinical Guideline CG48</a> 'Secondary prevention in primary and secondary care for patients following a myocardial infarction' is expected to be published in November 2013.</p> <p>An update of <a href="#">Clinical Guideline CG67</a> 'Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease' is expected to be published in July 2014.</p>
AstraZeneca	N/A	We would request AstraZeneca to be included as a commentator through manufacturing one of the comparators, ticagrelor.	Comment noted. Manufacturers of technologies currently indicated for the prevention as opposed to the treatment of acute coronary events are included in the TA210 appraisal. The review proposal is for clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events.
British Cardiovascular Society	Agree	On behalf of the British Cardiovascular Society Guidelines and Practice Committee, we agree with the NICE proposal for the above TA Guidance no.210.	Comment noted

Respondent	Response to proposal	Details	Comment from Technology Appraisals
MHRA	Noted	<p>Clopidogrel</p> <p>The current granted SPC indications are not exactly the same as the guidance recommendation, however there are preventative indications following MI and established peripheral arterial disease. The currently licensed indications for clopidogrel on EMC are confirmed to be a correct record. There are no safety issues currently ongoing.</p> <p>Modified release dipyridamole</p> <p>The current granted SPC indications are not exactly the same as the guidance recommendation, however the indications include secondary prevention of ischaemic stroke and transient ischaemic attacks either alone or in conjunction with aspirin. The currently licensed indications for dipyridamole on EMC are confirmed to be a correct record. There are no safety issues currently ongoing.</p>	Comments noted.
Bracknell and Ascot CCG	Agree	Bracknell & Ascot CCG are in agreement with NICE TA210 being moved to the static list.	Comment noted

Respondent	Response to proposal	Details	Comment from Technology Appraisals
Royal College of Nursing	No Comments	This is just to let you know that the feedback I have received from nurses working in this area of health suggest that there are no comments to submit on behalf of the Royal College of Nursing to inform on the review proposal of the above technology.	
Royal College of Physicians	Agree	Please take this email as confirmation that the RCP agrees with the NICE appraisal for the review	Comment noted
Association of British Neurologists	Agree	The ABN agrees with NICE that there is no additional evidence relevant to this particular technology appraisal. However, there are recently completed and on-going randomised trials of antiplatelet regimens for the prevention of vascular occlusive events following an ischaemic stroke or TIA that will impact on the most appropriate choice of antiplatelet regimen for these patients. These trials include the recently published Chinese CHANCE trial (New Engl J Med 2013) and the on-going POINT and TARDIS trials. The ABN believes that incorporation of the results of these and other relevant trials into guidance from NICE on antiplatelet treatment after ischaemic stroke or TIA would be appropriate.	Comments noted. An update of <a href="#">Clinical Guideline CG48</a> 'Secondary prevention in primary and secondary care for patients following a myocardial infarction' is expected to be published in November 2013.  An update of <a href="#">Clinical Guideline CG67</a> 'Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease' is expected to be published in July 2014.
The Vascular Society	Agree	The Vascular Society is happy for you to move this proposed review of guidance to the "static list" in view of the lack of new evidence	Comment noted

Respondent	Response to proposal	Details	Comment from Technology Appraisals
United Kingdom Clinical Pharmacy Association	Agree	UKCPA believe that the decision to move TA210 to the static list of technology appraisals is appropriate	Comment noted

**No response received from:**

<p><u>Manufacturers/sponsors</u></p> <ul style="list-style-type: none"> <li>• Actavis (clopidogrel)</li> <li>• Aspire Pharma (clopidogrel)</li> <li>• Beacon Pharmaceuticals (clopidogrel)</li> <li>• Boehringer Ingelheim (dipyridamole)</li> <li>• Sandoz (clopidogrel)</li> <li>• Sanofi (clopidogrel)</li> <li>• Teva UK (clopidogrel)</li> <li>• Wockhardt UK (clopidogrel)</li> </ul> <p><u>Patient/carer groups</u></p> <ul style="list-style-type: none"> <li>• Action Heart</li> <li>• Afiya Trust</li> <li>• Anticoagulation Europe</li> <li>• Black and Ethnic Minority Diabetes Association</li> <li>• Black Health Agency</li> <li>• Blood Pressure UK</li> <li>• British Cardiac Patients Association</li> </ul>	<p><u>General</u></p> <ul style="list-style-type: none"> <li>• Allied Health Professionals Federation</li> <li>• Board of Community Health Councils in Wales</li> <li>• British Cardiovascular Industry Association</li> <li>• British National Formulary</li> <li>• Care Quality Commission</li> <li>• Commissioning Support Appraisals Service</li> <li>• Department of Health, Social Services and Public Safety for Northern Ireland</li> <li>• Diabetes UK Cymru</li> <li>• Healthcare Improvement Scotland</li> <li>• National Association of Primary Care</li> <li>• National Pharmacy Association</li> <li>• NHS Alliance</li> <li>• NHS Commercial Medicines Unit</li> <li>• NHS Confederation</li> <li>• Scottish Medicines Consortium</li> </ul>
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- Cardiac Risk in the Young
- Coronary Prevention Group
- Diabetes Research and Wellness Foundation
- Diabetes UK
- Different Strokes
- Equalities National Council
- Heart Care Partnership
- HEART UK
- Independent Age
- Muslim Council of Britain
- Muslim Health Network
- Network of Sikh Organisations
- Somerville Foundation (formerly known as Grown Up Congenital Heart Patients Association)
- South Asian Health Foundation
- Specialised Healthcare Alliance
- Stroke Association
- Surya Foundation

#### Professional groups

- Association for the Study of Obesity
- Association of British Clinical Diabetologists
- British Association for Nursing in Cardiovascular Care
- British Association for Services to the Elderly
- British Association of Stroke Physicians
- British Atherosclerosis Society
- British Cardiovascular Intervention Society
- British Geriatrics Society
- British Heart Foundation
- British Nuclear Cardiology Society

#### Comparator manufacturers

- Actavis (aspirin)
- Boehringer Ingelheim (aspirin)
- GlaxoSmithKline (aspirin)
- Intraparm Laboratories (aspirin)
- Pfizer (aspirin)
- Reckitt Benckiser (aspirin)
- Teva UK (aspirin)
- Thornton & Ross (aspirin)
- Wockhardt UK (aspirin)

#### Relevant research groups

- Antithrombotic Trialists' (ATT) Collaboration
- British Society for Cardiovascular Research [BCS affiliated]
- Cardiac and Cardiology Research Dept, Barts
- Central Cardiac Audit Database
- Cochrane Heart Group
- Cochrane Metabolic & Endocrine Disorders Group
- Cochrane Peripheral Vascular Diseases Group
- Cochrane Stroke Group
- CODA
- 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

#### Assessment Group

- British Society for Haematology
- British Society For Heart Failure
- British Society of Cardiovascular Imaging
- British Vein Institute
- College of Emergency Medicine
- Diabetes Specialist Nurses
- Heart Rhythm UK
- National Diabetes Nurse Consultant Group
- Primary Care Cardiovascular Society
- Primary Care Diabetes Society
- Primary Care Neurology Society
- Royal College of General Practitioners
- Royal College of Pathologists
- Royal Pharmaceutical Society
- Royal Society of Medicine
- Society for Cardiological Science and Technology
- Society for Endocrinology
- UK Health Forum (formerly National Heart Forum)

Others

- Department of Health
- NHS England
- NHS South Devon and Torbay CCG
- Welsh Government

- Assessment Group tbc
- National Institute for Health Research Health Technology Assessment Programme

Associated Guideline Groups

- National Clinical Guidelines Centre

Associated Public Health Groups

- Public Health England
- Public Health Wales NHS Trust

**GE paper sign-off:** Frances Sutcliffe, Associate Director – Technology Appraisals Programme

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