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PRESS RELEASE

NICE publishes final <u>draft</u> guidance on clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events

NICE has today (21 October) published final **draft** guidance recommending the wider use of clopidogrel for the prevention of occlusive vascular events (ischaemic stroke, transient ischaemic attack [TIA] or heart attack) in people who have previously had an ischaemic stroke, or who have been diagnosed with a condition called peripheral arterial disease (PAD). The draft guidance also applies to people who have cardiovascular disease in more than one vascular site (multivascular disease), which puts them at high risk of subsequent occlusive vascular events.

The draft guidance, which updates previous NICE guidance published in 2005, recommends:

- Clopidogrel (initiated with the least costly licensed preparation) as an option for people who have had an ischaemic stroke, who have PAD or who have multivascular disease. Clopidogrel is only recommended as an option for people who have had a heart attack if aspirin is contraindicated or not tolerated.
- Modified-release dipyridamole plus aspirin as an option for people who have had a (TIA). For people who have had an ischaemic stroke, modified-release dipyridamole plus aspirin should only be used where clopidogrel is contraindicated or not tolerated.

 Modified-release dipyridamole alone as an option for people who have had an ischaemic stroke only where treatment with aspirin and clopidogrel is contraindicated or not tolerated.

Strokes and heart attacks occur when a blood vessel becomes blocked, usually as a result of a build-up of fatty deposit on the wall of the artery (called atherosclerosis) and the flow of blood through it is restricted. When an area of fatty deposit breaks off in one of the arteries, a chain of events is set off that can lead to blood clots forming and blocking the already narrowed artery. If the blood supply to the brain is affected, the result can be a stroke (either an ischaemic stroke if it happens for more than 24 hours, or a TIA if it happens for a shorter time). If the blood supply to the heart is affected, a heart attack can result. PAD is caused by a narrowing of the arteries in the arms or legs and people with the disease are at high risk of heart attack or stroke.

Professor Peter Littlejohns, Clinical and Public Health Director at NICE, said:

"Today's draft guidance draws on two major studies conducted since original NICE guidance on the use of clopidogrel and modified-release dipyridamole plus aspirin for the prevention of occlusive vascular events was published in 2005. Although both new studies were supportive of the earlier NICE guidance conclusions, the availability of clopidogrel as a generic preparation and the subsequent marked fall in its price, has meant that the Committee is able to recommend that it is used more widely. There is also evidence that both clopidogrel and modified-release dipyridamole continue to provide benefit beyond the two years previously suggested and this is reflected in the draft guidance published today.

He continued: "Heart attacks and strokes are some of the biggest killers and causes of disability in England and Wales and people who have had one heart attack or stroke are at a greater risk of having another. Today's draft guidance for clopidogrel and modified release dipyridamole has the potential to have a significant impact on the treatment of many thousands of patients in England and Wales."

The proposed guidance is with consultees, who now have the opportunity to appeal. Until NICE issues final guidance, NHS bodies should continue to follow the existing NICE guidance on the use of these drugs.

Ends

Notes to Editors

About the guidance

- The draft NICE guidance on the use of clopidogrel and modified-release dipyridamole for the prevention of occlusive vascular events is available on the NICE website at http://guidance.nice.org.uk/TA/WaveR/19
- 2. The existing NICE guidance (technology appraisal 90) is available on the NICE website at http://guidance.nice.org.uk/TA90.
- 3. Clopidogrel (Plavix, Sanofi-Aventis, Bristol-Myers Squibb) is an irreversible adenosine diphosphate-receptor antagonist with antiplatelet properties. It has a marketing authorisation for the prevention of atherothrombotic events in adults who have had a MI (from a few days until less than 35 days), ischaemic stroke (from 7 days until less than 6 months) or established peripheral arterial disease. The cost of generic clopidogrel is £3.40 for 30 days. Clopidogrel is not licensed for the treatment/prevention of transient ischaemic attacks and therefore recommendations could not be made about the use of clopidogrel in this patient population.
- 4. Modified-release dipyridamole (Persantin Retard and Asasantin Retard [combined with aspirin], Boehringer Ingelheim) has both antiplatelet and vasodilating properties. It has a marketing authorisation for the secondary prevention of ischaemic stroke and transient ischaemic attacks, either alone or in conjunction with aspirin. The 30 day cost of treatment with modified-release dipyridamole plus aspirin is £7.50.
- 5. In the UK, it is estimated that each year 98,000 people have a first ischaemic stroke, as many as 65,000 people have a TIA and 146,000 have a heart attack (or myocardial infarction MI). In addition, it is estimated that approximately 850,000 people aged 55-75 years have evidence of lower limb PAD. Stroke and MI are associated with a high morbidity and mortality. Some 30% of people die from their first MI. After a stroke, approximately 23% of people die within 30 days and the overall 3 year survival rate is only 30-40%. Stroke is also the leading cause of disability in the UK, with about 25-30% of people who survive a stroke remaining permanently disabled.

About NICE

- 6. The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.
- 7. NICE produces guidance in three areas of health:
- public health guidance on the promotion of good health and the prevention of ill
 health for those working in the NHS, local authorities and the wider public and
 voluntary sector
- **health technologies** guidance on the use of new and existing medicines, treatments, procedures and medical technologies within the NHS
- **clinical practice** guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.