1 **Reason for the review**

In the UK, low dose aspirin (75mg) is licensed for the prevention of thrombotic cerebrovascular or cardiovascular disease in patients who already have established vascular disease i.e. **secondary** prevention. Although aspirin is also used in primary prevention, this is **not** a licensed indication. Furthermore, recent studies have looked at the use of low dose aspirin in patients with no history of vascular disease. The outcomes of these studies have thrown considerable doubt on the use of low dose aspirin in primary prevention. Specifically, the small but serious risk of bleeding was found to outweigh any clinical benefits of aspirin in primary prevention. This new data has led the MHRA to issue a Drug Safety Alert (October 2009) which concluded that:

- Low dose aspirin should be restricted for use for the licensed indication of **secondary prevention** of vascular disease only.

If aspirin is to be used for primary prevention (unlicensed), then the risk/benefit situation of gastro-intestinal bleeding/risk of vascular disease should be assessed for each patient.

A further review in the DTB (November 2009) stated: **“we believe that the currently available evidence does not justify the use of low dose aspirin for the primary prevention of cardiovascular disease in apparently healthy individuals, including those with elevated blood pressure or diabetes; this is because of the potential risk of serious bleeds and lack of effect on mortality.”**

Further to its cardioprotective effects, data also exists to suggest that daily low-dose aspirin may confer protection from cancer. However, a National Prescribing Centre rapid review of the most recent and largest meta-analysis on this topic has concluded **“it is still premature to consider routine administration of daily aspirin to reduce the risk of developing cancer or of dying from it, especially when balancing the benefits against risks of taking aspirin, (particularly in the first few years). Indeed, this study is hypothesis generating and not hypothesis testing. A well-designed, prospective RCT, with a full intention-to-treat analysis and long-term follow-up over several years would ideally be required to establish whether or not aspirin has a place in preventing cancer.”**

In light of all available evidence, all patients who are currently being prescribed aspirin for primary prevention, including hypertensive and diabetic patients (in line with SIGN 116, March 2010) should be reviewed. If a proton pump inhibitor (PPI) has been co-prescribed with aspirin for gastro-protection, then that should also be discontinued. Evidence to support the continuation of aspirin in these patients to reduce their risk of developing cancer is not yet strong enough, particularly with regards risks versus benefits, to support this intervention. Therefore, this should not ordinarily be regarded as a reason to continue aspirin where it is being used for primary prevention of cardiovascular or cerebrovascular disease.

Any unlicensed use of aspirin, be it for primary prevention of cardiovascular disease, cerebrovascular disease or cancer, should only be continued following careful discussion with the patient of the risks versus the benefits of such an intervention and only after informing them that is an unlicensed use of the medicine.

2 **Inclusion Criteria**

Those patients who are **not eligible** for aspirin therapy:

Search for all patients who are receiving any dose of any aspirin preparation and who have **not** had a previous vascular event (as indicated in the ‘exclusion criteria’).
3 Exclusion Criteria.

Those patients who **are eligible** for aspirin therapy:

- Patients with a history of cardiovascular events - see Appendix 2 for further details.
- Patients with a history of cerebrovascular events and for whom treatment with clopidogrel is not appropriate – see Appendix 2 for further details
- Patients with terminal cancer
- Patients who are using aspirin as an analgesic (a key indication here is migraine for which it is one of the recommended treatment options in the NHS Dumfries & Galloway Joint Formulary)
- Any patient for whom aspirin is still considered necessary by GP
- Any individual patient exclusions deemed necessary by the GP e.g. patients who are deemed not to be open to change, as judged by the GP

4 Preparation and planning

Implementation of the audit in selected GP practices by the Prescribing Support Team is as follows:

- Protocol to be discussed with all GPs in the practice to ensure that agreement to proceed is reached
- Computer search of all patients according to the inclusion criteria
- Review of patients medical notes and repeat prescribing records
- A list produced of patients taking aspirin 75mg who are eligible to have treatment discontinued. Some of these patients may also be prescribed a PPI (omeprazole, lansoprazole etc) for the purpose of gastroprotection (whilst on aspirin), which may also be discontinued.
- Patients who have a PPI stopped should have Gaviscon Advance added to their repeat record for the management of rebound acid secretion. The ongoing need for this should be assessed after 3 months.
- List of eligible patients to be checked by GP(s)
- Letters to be sent to eligible patients and the ‘stop’ to be undertaken on the computer system (Appendix 1)

5 Action

Letters written to all patients outlining the reasons for stopping their medication to ensure they are fully informed and given an opportunity to discuss this with either their GP or practice pharmacist. (Appendix 1)

Admin. staff in practices to be made aware of discontinuation(s) of repeat medication.

Report for practices will include number of stops made by the pharmacist/technician and projected cost savings as a result of the recommendations.

Review to be undertaken by:  
GP Authorisation:  
Date:
Appendix 1: Patient letter if stopping Aspirin 75mg treatment.

Patient name
Address

Dear Mr/Mrs __________

Recent changes have been made to the prescribing guidelines for aspirin in the UK. As a result of this, NHS Dumfries and Galloway are currently reviewing all patients prescribed aspirin 75mg tablets.

Aspirin is used to ‘thin the blood’ and in that way it helps to prevent conditions such as heart attack and stroke. However, as with all medicines, aspirin has some undesirable side effects. It has recently been decided that due to these potentially serious side effects (e.g. bleeding from the stomach), aspirin will only now be prescribed for those patients who have angina or who have already suffered a stroke or heart attack. For patients such as yourself (who have not suffered one of these conditions) aspirin is no longer recommended. We have therefore discontinued your aspirin 75mg tablets with the approval of your doctor and it will no longer appear on your ‘repeat medication list’. If you were given an additional medicine with your aspirin to protect your stomach, then this will also be discontinued and replaced, for a short period of time, with a medicine called Gaviscon Advance. It is unlikely that you will need to use this, but it has been made available to you should you need it to control any symptoms of heartburn or indigestion that occur in the short-term as a result of stopping the medicine that has been protecting your stomach. All of this has been done in the interests of patient safety and you should be reassured that the advice comes from good clinical studies and experts in this area.

Should you have any queries, please contact the Surgery on the number above or, alternatively, you can contact a member of the Prescribing Support Team on xxxxxx

Yours sincerely

Name

Prescribing Support Technician
On behalf of the Doctors
Aspirin 75mg Discontinuation Project - Audit Data Collection Sheet

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Appendix 2: Patient exclusions

NB. This is not an exhaustive list. If there is any doubt as to a patient's medical history, please refer to a pharmacist or GP.

- **Cardiovascular Disease:**

  Patients with a history of acute coronary syndrome (ACS), pre-infarction syndrome, myocardial infarction (sometimes referred to as MI, STEMI, non-STEMI, NSTEMI, inferior MI), angina, ischaemic heart disease (IHD), coronary artery occlusion/narrowing, atherosclerosis, stenosis, atrial fibrillation.

  Patients who have had a coronary artery bypass graft (CABG), percutaneous coronary intervention (PCI), percutaneous transluminal balloon angioplasty, coronary artery stenting, coronary angioplasty or other surgery to improve blood flow to the heart, carotid artery disease. Patients with a history of aortic aneurysms, aortic stenosis or valve replacements should be discussed with a pharmacist.

  Patients prescribed anti-anginal medication e.g. nitrate sprays/tablets, nicorandil, ivabradine or ranolazine (suggesting existing cardiovascular disease).

- **Cerebrovascular Disease:**

  Treatment with clopidogrel alone is now recommended first line by both NHS D&G and NICE (TA210) in patients with a history of stroke, transient ischaemic attack (TIA), brain attack, cerebral infarction, cerebrovascular accident, transient cerebral ischaemia, cerebellar stroke, cerebral thrombosis, transient retinal thrombotic events and retinal artery events however, such patients are still eligible for treatment with aspirin and dipyridamole instead of clopidogrel for these conditions if one of the following applies:-

  - Patient has atrial fibrillation
  - Patient is receiving treatment for the prevention of occlusive events following coronary revascularisation
  - Patient is receiving treatment for the prevention of occlusive events following carotid artery procedures
  - Patient has giant cell arteritis
  - Patient has a history of clopidogrel intolerance

  Also eligible for treatment with aspirin are patients who have undergone carotid endarterectomy.
References