NHS Lincolnshire

Prescribing and Clinical Effectiveness Bulletin

Volume 5; Number 5 **March 2011**

What's new this month:

- **Vimovo, a new combination product containing naproxen and esomeprazole, is designated RED-RED (see page 3).**
- **Following NICE approval, dronedarone (Multaq) has been designated AMBER for the treatment of patients with non-permanent atrial fibrillation; a shared care guideline is required (see page 5).**
- **Updated NICE guidance on the use of clopidogrel and modified release dipyridamole for the prevention of occlusive vascular events is reviewed (see page 7).**
- **The importance of review of orlistat at 3 months to ensure achievement of continuation criteria is emphasized (see page 9).**
- **The shared care guideline on the use of nabilone for chronic neuropathic pain has been reviewed and updated (see page 10).**

CONTENTS

This bulletin has been created specifically to convey details of decisions taken at the Prescribing and Clinical Effectiveness Forum (PACEF) to all stakeholders across the Lincolnshire Healthcare Community in both primary and secondary care. Back issues of the *PACE Bulletin* and other PACEF publications are available through the NHS Lincolnshire website (www.lincolnshire.nhs.uk). Click on 'Commissioning' and follow the links to PACEF.

SUMMARY OF PACEF DECISIONS: JANUARY/ FEBRUARY 2011 UPDATE

Drug	Indication(s)	Traffic Light Status
Aluminium chloride 15%/ salicylic acid 2% gel (Hydrosal)	Treatment of axillary hyperhidrosis (unlicensed)	RED-RED
Dronedarone (Multaq) tablets 400mg	Licensed for the treatment of clinically stable adult patients with a history of, or current, non-permanent atrial fibrillation (AF) to prevent recurrence of AF or to lower ventricular rate	AMBER Shared care guideline required
Etonorgestrel (Nexplanon) 68mg subdermal implant	Contraception in women aged 18 to 40 years	GREEN
Naproxen 500mg/esomeprazole 20mg tablets (Vimovo)	Licensed for the symptomatic treatment of osteoarthritis (OA), rheumatoid arthritis and ankylosing spondylitis in patients at risk of NSAID associated gastric and or duodenal ulcers in whom lower doses of naproxen or other NSAIDs are not sufficient.	RED-RED
Sodium Chloride Nebuliser Solution 7% (Nebusal) (Hypertonic Saline)	A nebulised hypertonic sodium chloride solution used to mobilise lower respiratory tract secretions in mucous consolidation (e.g. cystic fibrosis)	AMBER No shared-care guideline required. Specialist initiation only.

RED-RED: This signifies that a product is **not recommended** for prescribing in **either** primary or secondary care. All new products are classified as RED-RED pending assessment by PACEF.
RED: This signifies that a product has been approved for use within secondary care, tertiary care or a primary care hosted specialist service only and **should not be routinely prescribed in primary care**. RED drugs may be used within ULHT or LPFT subject to approval for use within each Trust. ULHT and LPFT reserve the right to determine whether or not RED drugs will be used within their Trusts. RED classification does not automatically signify that a drug will be available within secondary/tertiary care.
AMBER: This signifies that a drug has been approved for use in primary care **subject to specialist initiation; a shared care guideline (SCG) may also be required**. The main purpose of the SCG will be to clearly define both specialist and GP responsibilities. Not all AMBER drugs that require SCGs are currently covered by formal documents; PACEF are working to rectify this.
GREEN: This signifies a product that is **approved for initiation in either primary or secondary care.**

REPORTING INCIDENTS TO THE NATIONAL PATIENT SAFETY AGENCY (NPSA)
The NPSA are keen to encourage the anonymous reporting of patient safety errors and systems failures both from healthcare professionals and patients. The National Reporting and Learning System (NRLS) has been set up to facilitate this process. Healthcare professionals can either report patient safety incidents through their local risk management scheme or directly into the NRLS using the eForm on the NPSA website. Please access www.npsa.nhs.uk for more information. **All healthcare professionals are encouraged to report incidents, errors and systems failures; the aim is to help the NHS to learn from things that go wrong.**

RAPID DRUG ASSESSMENT: ALUMINIUM CHLORIDE 15% /SALICYLIC ACID 2% GEL (HYDROSAL)

Aluminium chloride 15%/salicylic acid 2% gel (Hydrosal) is an unlicensed imported product used in the treatment of axillary hyperhidrosis. It is formulated without alcohol and presents a possible alternative for patients unable to tolerate standard alcohol-containing formulations (e.g. Driclor and Anhydrol Forte). Hydrosal is more expensive than alternatives and may be difficult to obtain in primary care.

PACEF Recommendation:
PACEF were reluctant to support a role for this product in primary care due to possible supply problems and its unlicensed status. After further discussion at ULH Drug and Therapeutics Committee, Hydrosal was designated RED-RED.

RAPID DRUG ASSESSMENT: SODIUM CHLORIDE 7% NEBULISER SOLUTION (NEBUSAL)

Short term administration of hypertonic sodium chloride nebuliser solution 7% (Nebusal) is reported to improve the rheological properties and transportability of sputum. It hydrates the airway surface and improves mucociliary clearance. At a dose of 4mL twice daily, it has been shown to be more effective than normal saline as an inhaled mucolytic agent in patients with cystic fibrosis (CF). In a double-blind, parallel-group trial, 164 patients with stable CF aged 6 years and over were randomly assigned to inhale 4mL of either hypertonic sodium chloride 7% or 0.9% saline twice daily for 48 weeks. The primary outcome measure, the rate of change in lung function during the 48 weeks of treatment, did not differ significantly between groups. However the absolute level of lung function, averaged over 4 to 48 weeks was significantly higher in the hypertonic saline group verses the control group. Also, in the hypertonic saline (HS) group, there were fewer exacerbations requiring intravenous antibiotics, the exacerbation free period was significantly longer, participants had significantly fewer days absence from school or work and significantly fewer adverse events. Cough can be a problem in the early stages of HS therapy, but typically resolves over time. To prevent or minimize airway narrowing, a bronchodilator must be given before the administration of the hypertonic saline.

Comparative costs reveal normal saline and HS to be comparably priced:

Drug	Dose	Cost/month
Sodium chloride 7% Nebuliser solution (Nebusal)	4mL BD	£27.00
Sodium chloride 0.9% Nebuliser solution	2.5mL BD	£26.85
Dormase alfa Nebuliser solution	2,500 Units (2.5mg) OD	£496.50

PACEF Recommendation:
Unlike dornase alfa, hypertonic saline does not, in the long term, improve lung function. However, evidence suggests that quality of life is improved with fewer pulmonary exacerbations, longer exacerbation free periods, fewer days' absence from school or work and fewer adverse events. HS is also inexpensive and safe with no increased infection risk. As a result of this, hypertonic sodium chloride nebuliser solution 7% (Nebusal) is designated AMBER with no shared care guideline required. Initiation should be by specialist only.

RAPID DRUG ASSESSMENT: NAPROXEN/ ESOMEPRAZOLE 500MG/20MG TABLETS (VIMOVO)

Vimovo is a fixed dose combination of the non steroidal anti-inflammatory drug (NSAID) naproxen plus the proton pump inhibitor (PPI) esomeprazole. It is licensed for the symptomatic treatment of osteoarthritis (OA), rheumatoid arthritis and ankylosing spondylitis in patients at risk of NSAID associated gastric and or duodenal ulcers in whom lower doses of naproxen or other NSAIDs are not sufficient.

PACEF Recommendation: NSAID choice
Prescribers are reminded of standard PACEF advice from *PACE Bulletin* Vol 2 No 7 (May 2008). In the treatment of OA, oral NSAIDs are third line options (after paracetamol and topical NSAIDs) that should only be used when absolutely necessary; the lowest effective dose for the shortest duration

should be used. In terms of product selection, low dose ibuprofen (e.g. 1200mg per day) has the lowest GI risk of standard NSAIDs. Low dose ibuprofen and naproxen (1000mg per day) have a lower thrombotic risk than other NSAIDs and coxibs; epidemiological data does not suggest an increased risk of myocardial infarction (MI) with either agent. Prescribers should consider low dose ibuprofen first line whenever an NSAID is indicated. Naproxen represents a suitable second line alternative, although GI risk is higher.

According to NICE Clinical Guideline 59: *Osteoarthritis – the care and management of osteoarthritis in adults* (February 2008), oral NSAID/Cox-2 inhibitor therapy should be **co-prescribed with a PPI,** choosing the one with the lowest acquisition cost. The NICE economic model used to determine the cost-effectiveness of this strategy used generic omeprazole 20mg capsules, although generic lansoprazole capsules are comparable in price.

PACEF Recommendation: Concurrent NSAID/PPI prescribing and PPI choice
PACEF recommend that all repeat and ongoing oral NSAID and Cox-2 inhibitor prescribing in people aged 55 and over should be supported with a concurrent PPI. Either generic lansoprazole capsules (recommended dose 15mg to 30mg daily) or generic omeprazole capsules (recommended dose 20mg daily) should be prescribed. Generic omeprazole capsules 20mg once daily currently represent the lowest cost option (£1.68 per month). These recommendations do not extend to acute or infrequent scripts.

Considering all of this, is Vimovo a rational or cost-effective combination?

Vimovo is a fixed dose combination with each tablet containing 500mg of naproxen and 20mg of esomeprazole. The standard dose is one tablet twice daily. While naproxen is one of the PACEF preferred NSAIDs, concern for cost-effectiveness would normally necessitate the choice of generic omeprazole or generic lansoprazole as the preferred PPIs for gastroprotection. The cost comparison below illustrates the significant price differences between generic ibuprofen or generic naproxen plus generic lansoprazole or omeprazole versus Vimovo:

Drug	Dose	Cost 28 days
Ibuprofen tablets	400mg to 800mg three times daily	£1.82 to £3.64
Naproxen tablets	500mg twice daily	£3.38
Naproxen tablets EC	500mg twice daily	£5.17
Omeprazole capsules	20mg daily	£1.68
Lansoprazole capsules	15 to 30mg daily	£1.37 to £2.08
Esomeprazole tablets(Nexium)	20mg daily	£18.50
Esomeprazole tablets(Nexium)	40mg daily	£25.19
Naproxen 500mg/esomeprazole 20mg tablets (Vimovo)	One tablet twice daily	£13.95

PACEF Recommendation:
Standard PACEF advice is to use ibuprofen as the first line NSAID of choice and naproxen second line. Either generic omeprazole capsules or lansoprazole capsules are the preferred PPIs for concurrent gastroprotection. Where gastroprotection is required, the NSAID and PPI components should be prescribed separately and generically. Vimovo tablets are significantly more expensive than the recommended combinations and should not be prescribed. Designation: RED-RED.

RAPID DRUG ASSESSMENT: ETONOGESTREL (NEXPLANON) 68MG SUBDERMAL IMPLANT

Nexplanon is an etonogestrel-releasing contraceptive implant which provides contraceptive cover for up to three years; it has been launched to replace the Implanon contraceptive implant which has been discontinued.

Figures from the Department of Health suggest that around 1.4 million women have used Implanon since its launch in 1999. Recently, the Medicines and Healthcare products Regulatory Agency (MHRA) caused a stir in the media when they reported that 584 pregnancies had occurred since launch in women that have received the Implanon implant. The MHRA also publicised problems associated with both the insertion and removal of the Implanon implant. Data from a nine year study indicated 0.049 pregnancies per 100 implants sold (i.e. 5 pregnancies per 100,000 women). This clinical data suggests that, if inserted correctly, the Implanon implant provides effective contraception for up to three years.

Nexplanon contains the same strength of etonogestrel as Implanon and has been shown to be bioequivalent, with no difference in clinical efficacy or safety profile. It has the advantage of a re-designed applicator that should prevent the inadvertent loss of the implant prior to insertion; the new applicator also limits the depth and length to which the implant can be inserted. Barium sulphate has been added to the formulation to make the implant radio opaque thus making it much easier to locate the implant prior to removal and easier to check that it has been correctly inserted.

Nexplanon and Implanon are both the same price, and therefore the introduction of the new product should have no impact on current prescribing costs.

PACEF Recommendation:
Etonogestrel (Nexplanon) 68mg subdermal contraceptive implant is designated GREEN.

NICE TECHNOLOGY APPRAISAL 197: *DRONEDARONE FOR THE TREATMENT OF NON-PERMANENT ATRIAL FIBRILL*ATION (AUGUST 2010)

Key Recommendations

Dronedarone is recommended as an option for the treatment of non-permanent atrial fibrillation only in people:

- **whose atrial fibrillation is not controlled by first-line therapy** (usually including beta-blockers) (i.e. dronedarone is a second-line/third-line option), and
- **who have at least one of the following cardiovascular risk factors:** (1) hypertension requiring drugs of at least two different classes; (2) diabetes mellitus; (3) previous transient ischaemic attack, stroke or systemic embolism; (4) left atrial diameter of 50mm or greater; (5) left ventricular ejection fraction less than 40% (noting that the summary of product characteristics (SPC) does not recommend dronedarone for people with left ventricular ejection fraction less than 35% because of limited experience of using it in this group) or; (6) age 70 years or older and:
- **who do not have unstable New York Heart Association (NYHA) class III or IV heart failure.**

Notes

Dronedarone (Multaq) is licensed for the treatment of adult clinically stable patients with a history of, or current, non-permanent atrial fibrillation (AF) to prevent recurrence of AF or to lower ventricular rate. Evidence from a small number of short-term placebo-controlled randomised controlled trials (RCTs) indicates that, in patients with non-permanent AF, dronedarone prolongs the time to AF recurrence, reduces ventricular rate and may also reduce rates of hospitalisation (but not necessarily mortality). Only one study directly compares dronedarone to amiodarone; results from this study confirm that dronedarone is better tolerated than amiodarone, but less effective in preventing the recurrence of AF in the short-term. There is no data on long term safety of dronedarone nor is there any published comparative data against any other anti-arrhythmic drug. **A cost comparison confirms that dronedarone is significantly more expensive than alternative second/third line agents.**

Drug	Dose	28 day cost
Amiodarone tablets	200mg once daily	£2.22
Dronedarone (Multaq) tablets 400mg	**400mg twice daily**	**£63.00**
Flecainide tablets	50 to 150mg twice daily	£5.64 to £13.99
Propafenone tablets (Arythmol)	150 to 300mg three times daily	£6.87 to £13.08
Sotalol tablets	80 to 160mg twice daily	£1.91 to £4.66

Dronedarone is contra-indicated in unstable patients with NYHA class III and IV heart failure and is not recommended in stable patients with recent (1 to 3 months) NYHA Class III heart failure or with a left ventricular ejection fraction less than 35% (because of limited experience). The most common side effects are elevated blood creatinine levels, prolongation of the QT interval, bradycardia, GI events (diarrhoea and vomiting), rashes, pruritis, fatigue and asthenia. **Recent reports from the American Food and Drug Administration (FDA) have highlighted cases of rare, but severe liver injury, including two cases of acute liver failure leading to transplant, in patients treated with dronedarone. Most recently the MHRA *Drug Safety Update* (Vol 4 Issue 7, February 2011) has reported on both the risk of cardiac failure and hepatotoxicity with dronedarone. As well as concerns over severe liver injury already raised by the FDA, the MHRA also report a number of cases of new-onset heart failure associated with the drug.** Advice to healthcare professionals is as follows:

- Patients should be advised to remain vigilant for the symptoms of heart failure (HF) or worsening of existing symptoms (e.g. weight gain, dependent oedema, increased dyspnoea). If HF develops or worsens, consider suspending or discontinuing dronedarone.
- For patients prescribed dronedarone, liver function tests (LFTs) should be performed: before treatment; on a monthly basis for 6 months; at months 9 and 12 and periodically thereafter. Existing patients on dronedarone should be contacted within the next month, so that LFTs can be initiated in line with the programme detailed above.
- Patients should be advised to remain vigilant for the symptoms of liver injury (e.g. abdominal pain or discomfort, loss of appetite, nausea, vomiting, yellowing of the skin or whites of the eyes, darkening of the urine, itching or fatigue).

NICE have identified a role for dronedarone as a second or third line alternative to amiodarone in the rhythm control treatment pathway for paroxysmal and persistent AF. In patients with symptomatic paroxysms (with or without structural heart disease)

a standard beta-blocker (BB) should be the initial treatment, but dronedarone may have a third line role after second line Class 1c agents (such as flecainide or propafenone) and sotalol. **ULHT cardiologists have confirmed that dronedarone will only be considered in patients who have failed first line treatment with a beta blocker and an additional second line treatment such as sotalol or flecainide.**

PACEF Recommendations

Dronedarone (Multaq) is approved for initiation by a cardiologist within the context of the NICE TA and subject to locally agreed initiation criteria (see above) Designation: AMBER. A shared care guideline is in preparation and will be available shortly to support ongoing GP prescribing of dronedarone after cardiologist initiation. GPs should not accept prescribing responsibility for dronedarone except within the context of formal shared care. Further work supporting amiodarone shared care is also being undertaken as a matter of priority. Dronedarone and amiodarone cannot be considered as equivalent therapies due to significant differences in both effectiveness and toxicity.

NICE TECHNOLOGY APPRAISAL 210: *CLOPIDOGREL AND MODIFIED-RELEASE DIPYRIDAMOLE FOR THE PREVENTION OF OCCLUSIVE VASCULAR EVENTS* (DECEMBER 2010)

Key Recommendations

1.Clopidogrel is recommended as an option to prevent occlusive events:

- For people who have had an ischaemic stroke or who have peripheral arterial disease (PAD) or multi-vascular disease, or
- For people who have has a myocardial infarction (MI) only if aspirin is contraindicated or not tolerated.

2. Modified-release dipyridamole in combination with aspirin is recommended as an option to prevent occlusive vascular events:

- For people who have had a transient ischaemic attack (TIA) , or
- For people who have had an ischaemic stroke only if clopidogrel is contraindicated or not tolerated.

3. Modified release dipyridamole alone is recommended as an option to prevent occlusive vascular events:

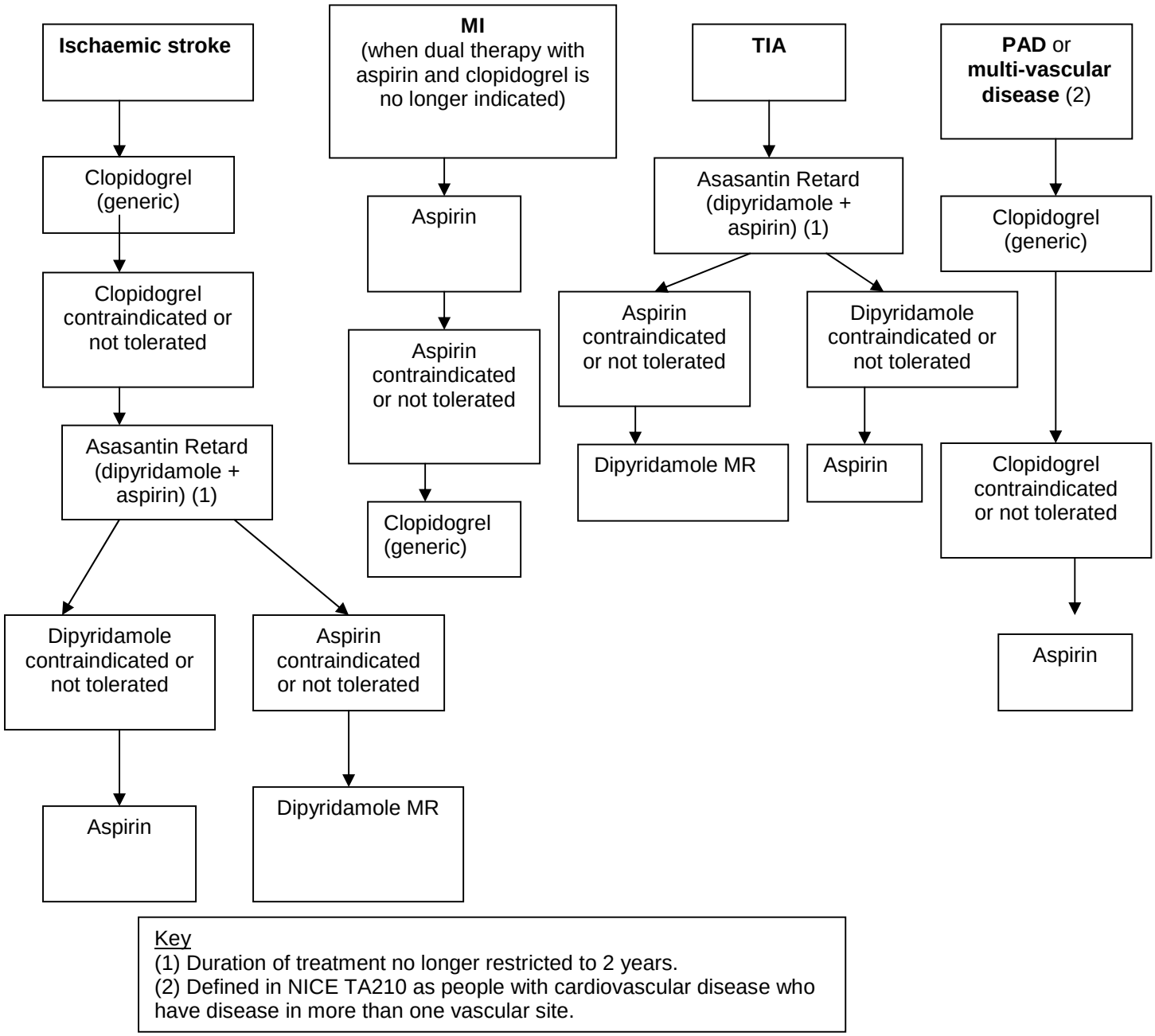
- For people who have had an ischaemic stroke only if aspirin and clopidogrel are contraindicated or not tolerated, or
- For people who have had a TIA only if aspirin is contraindicated or not tolerated.

4. Treatment with clopidogrel to prevent occlusive vascular events should be started with the least costly licensed preparation.

5. People currently receiving clopidogrel or modified-release dipyridamole either with or without aspirin outside the criteria in paragraphs1, 2 and 3 should have the option to continue treatment until they and their clinicians consider it appropriate to stop.

These guidelines are summarized in the following treatment algorithm:

Prevention of occlusive vascular events (NICE TA 210)



PACEF Recommendations:

Clopidogrel is now recommended first line for the prevention of events after ischaemic stroke, PAD and multi-vascular disease. These changes to current practice are mainly driven by the improved cost-effectiveness of clopidogrel resulting from falling generic prices. Standard PACEF advice is that all clopidogrel prescribing should be generic.

Previously the use of combination treatment with dipyridamole MR and aspirin following ischaemic stroke or TIA was limited to 2 years duration. This restriction has now been lifted based on the findings of the ESPRIT study. Combination treatment with dipyridamole MR and aspirin is now the second line option for ischaemic stroke. Where combination treatment with

dipyridamole MR and aspirin is indicated, the combination product Asasantin Retard (dipyridamole MR 100mg / aspirin 25mg) is recommended as it has a lower acquisition cost than the components prescribed separately (see cost comparison).
The TA presents a number of opportunities to ensure that patients benefit from the latest evidence. For example, patients currently treated with Asasantin Retard following an ischaemic stroke could benefit from a review and possible switch to clopidogrel, reducing both dose frequency and acquisition cost (see cost comparison). At current prices this would reduce monthly treatment costs by £4.30 per patient.

Cost comparison

	Daily dose	28 days
Clopidogrel tabs 75mg (generic)	One daily	£2.97
Plavix tablets 75mg	One daily	£33.27
Aspirin dispersible tabs 75mg	One daily	£0.85
Aspirin gastro-resistant tabs, 75mg	One daily	£0.94
Aspirin tablets, 75mg	One daily	£0.82
Dipyridamole MR 200mg caps (Persantin Retard)	One twice daily	£8.40
Asasantin Retard caps (dipyridamole MR caps 200mg + aspirin 25mg)	One twice daily	£7.27

NEW TRIALS IN BRIEF

REVIEW OF ORLISTAT PRESCRIBING

A small study presented at the Royal College of General Practitioners annual conference identified 84 patients in a single practice who had been prescribed orlistat between November 2008 and November 2009. Use of orlistat was audited against NICE CG43: 93% of patients were confirmed as meeting the NICE criteria for initiation; 67% of patients were left on treatment after 3 months despite failing to lose at least 5% of their initial body weight since starting treatment.

PACEF comment:
This study is limited because it reviewed orlistat prescribing in a small number of patients in a single practice. However similar results have been found in audits of orlistat use in some Lincolnshire practices. NICE CG43 recommends that orlistat should only be started in people with a BMI of at least 30 kg/m2 or at least 28kg/m2 if other risk factors are present. It should be used as part of an overall plan for managing obesity after diet, exercise and behavioural approaches have been tried. Treatment should continue beyond 3 months only if the person loses at least 5% of their initial body weight. Less strict goals may be agreed with people with type 2 diabetes. The decision to use orlistat for longer than 12 months (usually for weight maintenance) should be made after discussing potential benefits and limitations with the patient. The results of this audit suggest that regular orlistat review, particularly after the first three months of treatment, can help to ensure that only those patients experiencing genuine benefit continue with treatment.

Reference
Unpublished. Presented at the RCGP Annual Conference Harrogate 2010

CARDIOVASCULAR SAFETY OF NSAIDS

This network meta-analysis of large scale RCTs of NSAIDs was set up to investigate cardiovascular safety. The primary outcome was myocardial infarction. Secondary outcomes included stroke, cardiovascular death and death. 31 trials in 116,429 people exposed to naproxen, diclofenac, ibuprofen, celecoxib, rofecoxib, etoricoxib, lumiracoxib or placebo were included. Rofecoxib was associated with a statistically significant increased risk of MI (rate ratio 2.12, 95% CrI 1.26 – 3.56). The risk of stroke was increased with diclofenac (rate ratio 2.86; 95% CrI 1.09 – 8.36).The increase in stroke risk identified with ibuprofen (publicised in the media) did not achieve statistical significance (rate ratio 3.36; 95% CrI 1 – 11.6). Both etoricoxib and diclofenac were associated with the highest risk of CV death. Naproxen did not appear to have any statistically significant associations with any of the outcomes.

PACEF comment:
The long-term use of NSAIDs is associated with an increased risk of adverse cardiovascular events but the magnitude of the effect and the relative safety of different drugs is still debated. This large, well conducted meta-analysis has several limitations, but it adds to other data that suggests that naproxen has the best cardiovascular safety, whilst diclofenac and the coxibs appear to have a relatively poor CV profile. Media reports of this study focussed on the apparent three-fold increase in stroke associated with ibuprofen (rate ratio 3.36, 95% credibility interval 1 – 11.6). Although the point estimate suggests a three fold increase; the difference just fails to attain statistical significance. In addition the wide credibility intervals (effectively confidence intervals) quoted for the stroke risk suggests that the extent of any increase in risk is uncertain. Of the 31 trials included in the meta-analysis only two used ibuprofen and this was at a daily dose of 2.4g. The MHRA has previously advised that ibuprofen may be associated with a small thrombotic risk at high doses (2.4g) but evidence does not suggest an increased thrombotic risk at low doses (1.2g or less).

Reference
Trelle S et al. cardiovascular safety of non-steroidal anti-inflammatory drugs: network meta-analysis. BMJ 2011;342:c7086

SHARED CARE GUIDELINES

PACEF have approved the following SCG for use:

- Nabilone in the management of chronic neuropathic pain that has failed to respond to other first and second line treatments (review and update of an existing guideline).

All SCGs are now available on the NHS Lincolnshire website: (www.lincolnshire.nhs.uk). Click on 'Commissioning' and follow the links to PACEF.

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY: *DRUG SAFETY UPDATE (*DECEMBER 2010)

Fibrates: European Medicines Agency concludes first line treatment is not recommended

- The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of the four fibrates

bezafibrate, ciprofibrate, fenofibrate and gemfibrozil continue to outweigh their risks in the treatment of patients with blood lipid disorders.

- However, healthcare professionals should not prescribe them to newly-diagnosed patients with blood lipid disorders as first-line treatment, except for patients with severe hypertriglyceridaemia or patients who cannot take statins.

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Stephen Gibson
Head of Prescribing and Medicines Management
NHS Lincolnshire

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