

February
2009

impact

Changes to pharmacy contractors' submission document

When we introduced the new processing system in 2007 we changed the look of the FP34c submission document which pharmacy contractors send to us to make a claim for payment according to the Drug Tariff Part I, clause 5. We had feedback from pharmacy contractors that the FP34c needed to be clearer about how to sort and submit your batches. Towards the end of last year working with the Department of Health to review the FP34c we made a number of changes to the wording. We consulted with the Pharmaceutical Services Negotiating Committee (PSNC) on the changes. We wrote to all pharmacy contractors in December to let you know that we had updated the FP34c and that the new version should be used from January 2009 (December 2008 dispensed prescriptions).

The key changes we have made are:

1) Red Separator for BB and Calendar Pack Prescriptions

Orders for broken bulk and calendar pack prescriptions, where the quantity prescribed differs from the size of the pack or sub pack size and the prescribed quantity is dispensed, should be placed

on top of each of the relevant groups. For example exempt forms on top of the exempt group, chargeable forms on top of the chargeable group and old rate chargeable forms on top of the old rate chargeable group.

Based on contractor feedback we will supply red separators for you each month to help you identify these forms within each of the relevant groups.

2) Part 2 Declarations

We have included a note in the 'Total claim for Out of Pocket Expenses' to explain that you should only include the Out of Pocket Expense Claims within the account in the boxes provided. You do not need to include the cost of the drug, appliance or chemical reagent as this payment will be made against the relevant prescription form.

3) Submission document - condition and version to submit

We have added to the notes on page 1 about the condition of the form and the version to send us. Undamaged submissions documents are easier to scan and make your account number, submission month etc easier to identify. If you use a photocopy version or incorrect month's version this could result in delayed or incorrect payment.

4) Submission of account

We would like to clarify how to segregate and bundle your account to reduce your account preparation time. Ideally please segregate your account and bundle using elastic bands into the following groups:

- Exempt with the broken bulk and relevant calendar packs in exempt red separator
- Chargeable with broken bulk and relevant calendar packs in chargeable red separator
- Old rate chargeable with broken bulk and relevant calendar packs in old rate chargeable red separator

The groups should be banded together. This helps to prevent the possibility of the forms getting mixed up between leaving your premises and arriving at our office. We do not need you to use any other means to secure your forms such as adhesive tape, pins or staples.

5) Repeat dispensed prescriptions

You now only need to sort repeat dispensed prescription forms into prescriber order.

6) Repeat authorising forms

RA – Repeat Authorising Forms, must be separate from the remainder of the prescriptions within your account, as payment should not be made on these forms.

Help and guidance

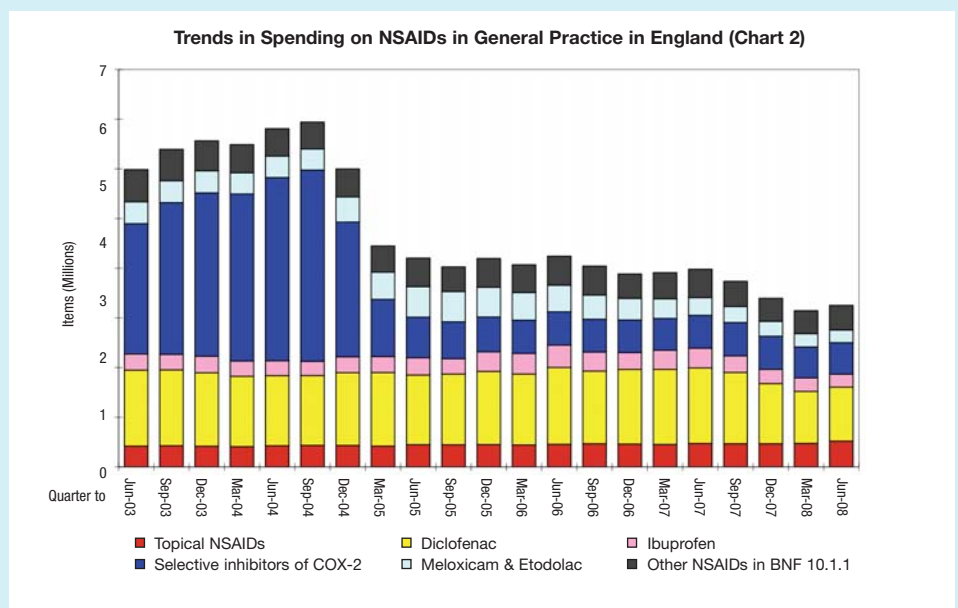
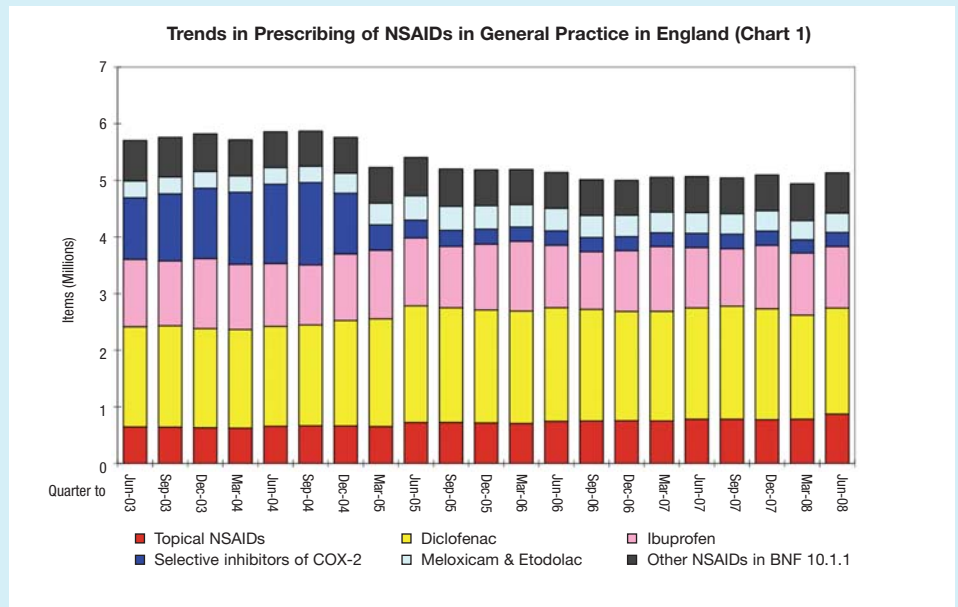
You can find further information and guidance on our new website www.nhsbsa.nhs.uk/prescriptions Or you can phone our Helpdesk on **0845 610 1171**.

Prescribing Review report on Prescribing of NSAIDs

The Prescribing Review report on Prescribing of Nonsteroidal anti-inflammatory drugs (NSAIDs), available to general practitioners in November 2008, is reproduced here for readers with an interest in patterns and trends of prescribing.

Nonsteroidal anti-inflammatory drugs (NSAIDs) inhibit cyclo-oxygenase enzymes and are used to manage a variety of acute and chronic conditions associated with pain and/or inflammation. All NSAIDs inhibit both COX 1 and 2 enzymes but most of the NSAIDs that have been developed in recent years show greater activity as inhibitors of COX 2.¹ These newer NSAIDs are often referred to as 'coxibs'. Selective inhibitors of COX-2 as defined in this article, meet the Medicines and Healthcare products Regulatory Agency (MHRA) definition of selective COX-2 inhibitors (celecoxib, etoricoxib, rofecoxib, valdecoxib and lumiracoxib), all other NSAIDs are classed as non-selective.² In 2006 the MHRA issued advice following a Europe-wide review of the cardiovascular (CV) safety of the selective inhibitors of COX-2 that suggested there was small increased risk of thrombotic events compared with placebo which increased with dose and duration.³ This article explores the patterns in NSAID prescribing since the publication of the MHRA review and the withdrawal of licensed products from the UK market, but excludes the use of both oral and topical NSAIDs bought as 'over the counter' products.

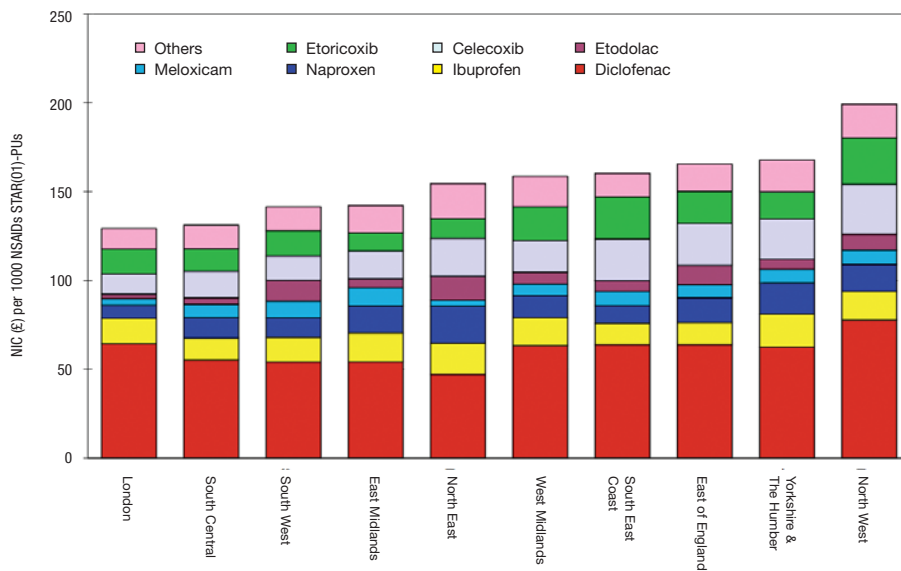
A standard approach to symptomatic pain management should follow the principles of the World Health Organization (WHO)



three-step analgesic ladder. Paracetamol and/or an NSAID can be used from step one of the WHO pain ladder onwards. Analgesics should be started at the 'step' most appropriate to the patient's level of pain, and doses should be titrated following regular re-assessment of response. Treatment of the underlying disease causing the pain may reduce the need for analgesics. Non-drug treatments should be maximised, particularly in chronic pain where psychological and psychosocial factors are important. The National Institute for Health and Clinical Excellence (NICE) recommends regular

dosing with paracetamol as first-line analgesia for osteoarthritis (OA).⁴ It is effective for short-term mild to moderate pain and is less likely than NSAIDs to cause gastrointestinal (GI) adverse effects. In patients with knee or hand OA, NICE also recommends use of a topical NSAID before an oral NSAID. Systematic reviews have found no important differences in efficacy between different NSAIDs in the management of musculoskeletal disorders⁵ therefore, when prescribing an NSAID, assessing differences in risk must be considered as well as patient preference and cost.

Variation Between Strategic Health Authorities in Spending on NSAIDs (Quarter to June 2008) (Chart 3)



Risk factors for upper gastrointestinal adverse effects

People are at high risk of serious NSAID-induced GI adverse events if they have one or more of the following risk factors: age 65 years or older (the risk is twice as high in men as in women); history of GI ulcer, bleeding, or perforation; concomitant use of drugs that increase the risk of GI adverse events; serious comorbidity, such as CV or renal disease; requirement for prolonged NSAID use; and use of the maximum recommended dose of an NSAID.⁶ A systematic review and meta-analysis investigated NSAIDs and serious GI complications.⁷ Pooled relative risks were calculated for different risk factors. NSAID users with advanced age or a history of peptic ulcer disease had the highest absolute risks for upper GI tract bleeding or perforation. Compared with patients aged 25 to 49 years, 60 to 69 year olds had 2.4 times the risk of a GI bleed or perforation, 70 to 80 years had 4.5 times the risk, and patients over 80 years had 9.2 times the risk. Potentially hazardous drug interactions may occur with NSAIDs. For example, people who are taking warfarin should ideally avoid taking NSAIDs, and people taking a selective serotonin reuptake inhibitor (SSRI) plus an NSAID are advised to seek urgent medical advice and stop NSAID use if a bleeding episode occurs.^{8,9} A recently published meta-analysis found that, in people older than 50 years taking an SSRI and an NSAID with no risk factors for upper GI bleeding, for every: 411 people treated with SSRIs, one person experienced upper GI bleeding (number needed to harm [NNH] = 411), 106 people treated with an SSRI and an NSAID together, one person experienced upper GI bleeding (NNH = 106).

Prevention and management of gastrointestinal adverse effects

To prevent GI adverse effects from oral NSAIDs several recommendations have been published:

- Use an alternative to an NSAID, e.g. in patients with OA: paracetamol with or without codeine, topical NSAIDs, and physical treatments;⁴
- Use only one NSAID at a time,¹⁰ and if aspirin is needed for CV protection, its use almost always has priority over use of an NSAID;
- Use the lowest NSAID dose that is compatible with symptom relief.

In people who are at increased risk of GI adverse effects and who require an NSAID, consider use of a gastroprotective drug. Proton pump inhibitors (PPIs) are effective at reducing the risk of NSAID-induced endoscopic gastric and duodenal ulcers, and are well tolerated. In contrast, standard doses of histamine₂-receptor antagonist (H₂RA) are not very effective in reducing the risk of NSAID-induced endoscopic ulcers. Misoprostol (800 micrograms daily) is the only prophylactic drug that has been shown to reduce the occurrence of clinically important ulcer complications, but its use is associated with significant adverse effects and poor compliance, particularly at high doses. Recent trials have influenced the NICE Osteoarthritis guideline development group to recommend that when offering treatment with an oral non-selective NSAID or a selective inhibitor of COX-2 (note: etoricoxib 60mg is not recommended), the drug selected should be co-prescribed with a PPI, choosing the one with the lowest acquisition cost.⁴

Risk factors for cardiovascular and renal adverse effects

The risk of serious cardiac or renal adverse events is increased in patients: with a history of, or risk factors for, CV disease; with renal impairment (e.g. creatinine clearance less than about 20mL/min); or over 65 years of age, even in the absence of CV or renal risk factors.^{11,12} Evidence from systematic reviews suggests that many NSAIDs are associated with an increased risk of CV adverse events.¹³ The risk for individuals is associated with treatment duration and is disproportionately increased in people who are at high risk for CV disease before starting treatment. The CHM,¹¹ MHRA,¹² and the National Prescribing Centre (NPC)¹ have recently summarized the evidence for CV thrombotic risks associated with selective inhibitors of COX-2 and non-selective NSAIDs based on systematic reviews and meta-analyses and concluded that:

- All selective inhibitors of COX-2 increase the risk of atherothrombosis by about 3 events per 1,000 people per year (compared with placebo).
- Naproxen 1,000 mg daily has a lower thrombotic risk than selective inhibitors of COX-2, and overall, epidemiological data do not suggest an increased risk of myocardial infarction (MI).
- Ibuprofen may have a small thrombotic risk at high doses (i.e. 2,400 mg daily), but at lower doses (i.e. 1,200 mg daily or less) epidemiological data do not suggest an increased risk of MI.
- Diclofenac 150 mg daily has a thrombotic risk profile similar to etoricoxib (and consequently, the NPC has been encouraging prescribers to review patients taking diclofenac).
- There is less evidence for other NSAIDs, but they may all be associated with a small risk of thrombotic events.

Regarding the risk of cardiorenal adverse effects (e.g. hypertension, heart failure), NSAIDs have been shown in three systematic reviews to increase blood pressure (BP) and the risk of hypertension.¹⁴⁻¹⁶ The risk of increasing BP with an NSAID is probably higher between susceptible and non-susceptible individuals than between one NSAID and another. In particular, the MHRA have advised that etoricoxib should not be initiated in people whose hypertension is not under control and careful monitoring of BP is advised.

Chart 3 shows the variation in spending on NSAIDs across Strategic Health Authorities (SHAs) for April to June 2008. There is a two fold difference in spending between SHAs on selective inhibitors of COX-2 (celecoxib, etoricoxib) with a variation of between 18% to 29% of the total spend. Etodolac shows the greatest variation between SHAs with a five fold difference and a range of 2% to 9% of total spend.

Prescribing Data (reporting quarter = April-June 2008, index quarter = April-June 2003)

Prescribing of NSAIDs (excluding topical) has decreased by 16% (to 4.3 million items) and costs have fallen 51% (to £27.3 million) in the last five years. Diclofenac is the most commonly prescribed NSAID, 1.9 million items per quarter (a 6% increase) costing £10.9 million (a 29% decrease). It accounts for 44% of all NSAID items and 40% of the cost. Ibuprofen accounts for 25% (1.1 million) of NSAID items (a 9% decrease) and 10% (£2.6 million) of the cost (a 19% decrease). Naproxen items have increased by 54% to 427,000, costing £2.3 million (a 19% increase). Prescribing of selective inhibitors of COX-2 has decreased by 77% in the last five years (to 248,000 items, £6.4 million). This represents 6% of NSAID items and 23% of

the cost. Prescribing of celecoxib has fallen 74% to 127,000 items, costing £3.4 million (a decrease of 67%). Etoricoxib items have increased by 36% (121,000 items, £3 million). Meloxicam items remains stable, increasing by 5% to 261,000 items with a reduction in cost of 64% (£1.3 million). Items for etodolac have increased by 66% (to 80,000) and costs by 47% (£1.3 million). Prescribing of rubefaciants has increased by 17% (to 1.3 million items) and cost has increased by 21% (to £7.5 million). Topical NSAIDs account for 872,000 of these items, £5.2 million.

Prescribing of paracetamol and paracetamol combination products has increased by 8% (8.8 million items) and costs have risen by 62% (£35.4 million). Paracetamol is the most commonly prescribed at 4.2 million items, an increase of 48%. The cost has more than trebled to £10.1 million. Paracetamol with codeine has increased by 49% (3.5 million items, £19.7 million). Prescribing of paracetamol with dihydrocodeine increased by 6% (1 million items), cost increased 18% (£3 million). Prescribing of co-proxamol has reduced by 95% to 92,000 items following the withdrawal of its licence, with spending decreasing by only 7% (£2.6 million).

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Key Messages

If a person is at high risk of developing an adverse effect, ideally an alternative to an oral NSAID should be found e.g. paracetamol alone or with codeine, topical NSAIDs and physical treatments. Failing this use one NSAID at a time at the lowest dose compatible with symptom relief.

People are at high risk of upper GI adverse events if they are aged 65 years or older; have a history of GI ulcer, bleeding or perforation; take other drugs that increase the risk of GI events; require prolonged use of NSAIDs or a maximum dose of a NSAID.

PPIs are the most effective drugs for reducing the risk of NSAID-induced endoscopic gastric and duodenal ulcers, taking into account adverse effects and compliance issues.

Most NSAIDs are associated with an increased risk of cardiovascular adverse events. The risk increases with increased treatment duration and in those people who already have cardiovascular disease before starting treatment.

Free Prescriptions for Cancer Patients

The Prime Minister announced in Autumn 2008 that people battling cancer will be entitled to free prescriptions from this year. Work is now going ahead to ensure patients are able to apply for exemption certificates by 1 April 2009, when the new arrangements take effect.

While the good news is that cancer patients will get free prescriptions, to do so, they still need to apply for an exemption certificate. Additionally, because exemption doesn't take effect until April, it is important that patients don't miss out on help with their prescription costs in the meantime.

Patient information – raising awareness

We know from feedback that patients enjoy the convenience of being able to access healthcare information at their local pharmacy or dispensing doctor. We would appreciate your help in:

- letting patients know about the new exemption from 1 April 2009
- making them aware of the support that is already available through prescription pre-payment certificates (PPCs) and the NHS Low Income Scheme.

Dispensing doctors

We'll be sending a pad of new FP92A application forms direct to each doctor via your practice for February. As soon as the form is available, it would be helpful if you could ask patients when they attend appointments if they have applied for an exemption certificate (to avoid patients being overlooked or duplicating applications already made through a Trust). If not, please give them an application form.

Patients with other conditions

Arrangements for patients applying for an exemption certificate with other medical conditions haven't changed, except that they should use the new version of the application form as soon as it is available.

Find out more

If you have any queries or concerns, please e-mail:
medicalproject@ppa.nhs.uk
for advice.



Remember there are other ways patients can get support before 1st April 2009

● NHS Low Income Scheme (claim form HC1)

The NHS Low Income Scheme provides help for those who don't automatically qualify for help with health costs such as prescription charges, but who find it difficult to pay. Anyone can apply using claim form HC1 as long as they don't have savings or capital of more than £16,000 (£22,250 for those permanently in a care home).

For anyone who has difficulty completing forms, we provide a form completion service - patients can call us on **0845 850 1166** and we will complete the form on their behalf.

● Pre-payment certificates (application form FP95)

Patients who have to pay for their prescriptions can save money with a pre-payment certificate (PPC). A PPC costs £102.50 for 12 months. This can be paid either up front in full, or by 10 monthly direct debit instalments of £10.25. A three month PPC for £27.85 is also available. Patients who will be exempt from next April may prefer to buy a three month PPC although refunds will be available after April in respect of complete months unexpired.

Either PPC can save money for anyone who needs more than 14 items in 12 months or more than 3 items in three months. For greater convenience, patients can apply:

- online at www.nhsbsa.nhs.uk
- by calling the PPC order line on **0845 850 0030**
- through a pharmacy registered to sell PPCs

