MONITORING OF NON-FORMULARY PRESCRIBING IN PRIMARY CARE

PostScRipt
from the
NHSGGC Area Drug & Therapeutics Committee
Issue 47 September 2008

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Website
http://www.ggcformulary.scot.nhs.uk

In PostScript 41 we highlighted the updated and agreed non-Formulary (NF) process. This policy offers a full interpretation of the exceptional situations when an NF medicine could be prescribed. It highlights in brief the principles of approval, the right of appeal and the need for monitoring and review. In PostScript 42 we highlighted the Appeals Process which can be used by senior clinicians when they feel a drug should be added to the Formulary.

A non-*Formulary* medicine is defined as any medicine, indication or formulation that is not included in the NHS Greater Glasgow & Clyde *Formulary*. This includes medicines which have not been accepted by the Scottish Medicines Consortium (SMC) or have not yet been evaluated. It may also apply to a *Formulary* medicine which is being used outside agreed local guidelines.

In acute care, a monitoring process has been in place for a number of years. It has been updated and streamlined to ensure information is passed through the directorate structures. There are copies of all relevant primary and acute care documents on Staffnet (**staffnet/Info+Centre/GGC+Formulary/default.htm**).

A corresponding monitoring process is being introduced to primary care and rollout across the CH(C)Ps started in August 2008. GPs are strongly encouraged to prescribe within the NHSGGC *Formulary*.

What is the primary care non-*Formulary* system?
The system is primarily designed as a quick way to enable GPs to flag up selected NF requests coming from the acute sector. It also allows GPs wishing to initiate these medicines themselves to demonstrate the rationale for use.

Why complete non-*Formulary* request forms?
In the acute sector, if a consultant wishes to prescribe or continue an NF medicine, they are asked to complete an NF request form prior to the medicine being supplied by the hospital pharmacy. However, there is no way of monitoring requests for NF medicines communicated verbally or by letter to GPs. Though prescribers in acute are reminded and encouraged to share with their GP counterparts the rationale for requesting an NF medicine, we know that this rarely happens in practice. By the GP completing this quick form, the relevant information is provided so that inappropriate NF requests originating from the acute sector can be raised and followed up within the acute sector at directorate level.

When do I need to complete a non-*Formulary* request form?
We are not asking you to complete a form every time you receive a request to initiate an NF medicine, as that would not be practical. Instead, we ask that one form, which should take 1-2 minutes to complete, is completed if you get a request, or wish to initiate one of the medicines from the Highlighted Non-*Formulary* Medicines List. The list is available at **staffnet/Info+Centre/GGC+Formulary/Formulary_NonFormularyInfo_RFAK_Sept07.htm** and currently includes:

- clopidogrel when used outside NHSGGC Antiplatelet Guidelines
- buprenorphine patch
- cilostazol
- escitalopram
- esomeprazole
- ezetimibe/simvastatin
- pregabalin except when prescribed to treat epilepsy
- Yasmin®.

I've completed the form, can I prescribe the medicine for the patient now?
That decision is entirely up to you. If the prescriber within acute has provided clear rationale for the choice in therapy, you may wish to prescribe, though you are under no obligation to do so. If no clear reasons for the choice have been given, you may consider discussing the request with the individual in the acute sector before making a decision.

What happens to completed forms?
You send the completed form to your CH(C)P Prescribing Lead. This allows them to understand the pressures you are under to prescribe these medicines. The Prescribing Lead collates information from the CH(C)P and passes it on to the *Formulary* Team. Trends are identified and issues are addressed at an appropriate level within the acute sector.

Reports on adherence to the Preferred List are produced on a quarterly basis and reported to the Medicines Use and Prescribing Education Subcommittee of ADTC and to Prescribing Leads. Baseline information indicates adherence to the Preferred List to be approximately 74%. Although adherence to the Total *Formulary* is not known (and would be impossible to monitor accurately because of the lack of information about associated indication), it is widely assumed that it will be considerably higher than 74%.

For all article references, check our website
www.ggcformulary.scot.nhs.uk

Alphabetical list of most recent ADTC decisions

For full details of SMC advice, visit **www.scottishmedicines.org** For NICE advice, visit **www.nice.org.uk** For previous ADTC decisions, visit **www.ggcformulary.scot.nhs.uk**

Drug	Indication under consideration (There may be other licensed indications)	NHSGGC decision	
Buprenorphine transdermal patches (BuTrans®)	Severe opioid responsive pain conditions which are not adequately responding to non-opioid analgesics.	Non-*Formulary.*	x
Clobetasol propionate 0.05% shampoo (Etrivex®)	Topical treatment of moderate scalp psoriasis in adults.	Total *Formulary.* Acknowledge new formulation.	✓
Clostridium botulinum neurotoxin type A (Xeomin®)	Symptomatic management of blepharospasm and cervical dystonia of a predominantly rotational form (spasmodic torticollis) in adults.	Total *Formulary.* Restricted to specialist use.	✓R
Epoetin alfa, epoetin beta and darbepoetin	Cancer treatment-induced anaemia.	Not added to the *Formulary* for this indication. NICE MTA142 states that routine use of these agents is generally not recommended. Specific circumstances are noted where use is accepted - see guidance.	x
Ferric carboxymaltose (Ferinject®)	Iron deficiency when oral preparations are ineffective or cannot be used.	Non-Formulary.	x
Fesoterodine fumarate (Toviaz®)	Symptomatic treatment of overactive bladder syndrome.	Non-*Formulary.*	x
Ibritumomab tiuxetan (Zevalin®)	Consolidation therapy after remission induction in previously untreated patients with follicular lymphoma.	Non-*Formulary.*	x
Infliximab (Remicade®)	Ankylosing spondylitis.	Non-*Formulary.* Infliximab in ankylosing spondylitis is no longer included in the Total *Formulary* as a result of NICE MTA143. This guidance supersedes previous SMC guidance in Scotland.	x
Lidocaine 5% medicated plaster (Versatis®)	Post-herpetic neuralgia.	Total *Formulary.* Restricted to use in patients who are intolerant of first line therapies for post-herpetic neuralgia or where these therapies have been ineffective.	✓R
Melatonin (Circadin®)	Monotherapy for short-term treatment of primary insomnia characterised by poor quality of sleep in patients aged 55 years or over.	Non-*Formulary.*	x
Natalizumab (Tysabri®)	Single disease modifying therapy in highly active relapsing multiple sclerosis.	Total *Formulary.* Restricted to specialist use in accordance with agreed local protocol and SMC restrictions.	✓R
Nebivolol (Nebilet®) (ADTC appeal)	Heart failure in elderly patients (>70 years).	Total *Formulary.* Restricted to specialist initiation in patients over the age of 70 years with confirmed chronic cardiac failure who fail to tolerate bisoprolol and carvedilol.	✓R
Omalizumab (Xolair®)	Additional therapy in adults and adolescents (12 years or above) with severe persistent allergic asthma.	Total *Formulary.* Restricted to specialist use in accordance with agreed local protocol and SMC restrictions.	✓R
Paricalcitol capsules (Zemplar®)	Prevention and treatment of secondary hyper-parathyroidism associated with chronic renal insufficiency (chronic kidney disease (CKD) Stages 3 and 4) patients and chronic renal failure (CKD Stage 5) patients on haemodialysis or peritoneal dialysis.	Non-*Formulary.*	x
Paricalcitol injection (Zemplar®)	Prevention and treatment of secondary hyperparathyroidism in patients with chronic renal failure undergoing haemodialysis.	Non-*Formulary.*	x
Pegylated interferon alfa 2b (ViraferonPeg®) injection in combination with ribavirin (Rebetol®)	Adult patients with chronic hepatitis C who have failed previous treatment with interferon alfa and ribavirin combination therapy or interferon alfa monotherapy.	Total *Formulary.* Acknowledge new indication. Restricted to use in accordance with Hepatitis MCN protocol.	✓R
Rabbit anti-human thymocyte immunoglobulin (Thymoglobuline®)	Prevention of graft rejection in renal transplantation.	Non-*Formulary.*	x
Rosuvastatin (Crestor®) (ADTC appeal)	Hypercholesterolaemia.	Total *Formulary.* Restricted to use in accordance with NHSGGC Lipid Lowering Guidelines - see p4. Doses of 40mg and above should only be initiated by, or on the advice of a specialist.	✓R
Sorafenib (Nexavar®)	Hepatocellular carcinoma.	Non-*Formulary.*	x
Tenofovir disoproxil (Viread®)	Chronic hepatitis B in adults with compensated liver disease, with evidence of active viral replication, persistently elevated serum alanine aminotransferase levels and histological evidence of active inflammation and/or fibrosis.	Total *Formulary.* Acknowledge new indication. Restricted to use in accordance with Hepatitis MCN protocol.	✓R
Teriparatide (Forsteo®)	Osteoporosis in men at increased risk of fracture.	Non-*Formulary* for this indication.	x
Topotecan (Hycamtin®)	Carcinoma of the cervix recurrent after radiotherapy and for patients with stage IVB disease in combination with cisplatin.	Total *Formulary.* Acknowledge new indication. Restricted to specialist use in accordance with regional protocol.	✓R
Trabectedin (Yondelis®)	Advance soft tissue sarcoma after failure or unsuitability of anthracyclines and ifosfamide.	Non-*Formulary.*	x
Tramadol capsules (ADTC appeal)	Moderate to severe pain.	Total *Formulary.* Restricted to use where simple analgesia has failed or is not tolerated. Excludes modified-release and combination preparations.	✓R
Venlafaxine (Efexor XL®)	Moderate to severe generalised social anxiety disorder/social phobia in adults.	Non-*Formulary* for this indication.	x
Vildagliptin/metformin (Eucreas®)	Type 2 diabetes mellitus patients who are unable to achieve sufficient glycaemic control at their maximally tolerated dose of oral metformin alone or who are already treated with the combination of vildagliptin and metformin as separate tablets.	Total *Formulary.* Acknowledge new combination. Restricted to specialist initiation only when the addition of a sulphonylurea is not appropriate for patients with insufficient control despite maximising metformin monotherapy.	✓R

✓= *Formulary* ✓R = *Formulary* (restricted) x = non-*Formulary* ? = awaiting final decision

Lidocaine 5% plaster (Versatis®) added to Total *Formulary* for the second-line treatment of post-herpetic neuralgia

Following a re-submission by the manufacturer, SMC has accepted lidocaine 5% plaster (Versatis®) for restricted use within NHS Scotland for the treatment of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia). The ADTC has accepted it for restricted *Formulary* use according to SMC advice (August 2008).

Important points to note

- Prescribing for indications other than post-herpetic neuralgia remains unlicensed and non-*Formulary*.
- It is restricted to use in patients who are intolerant of first-line systemic therapies for post-herpetic neuralgia or where these therapies have been ineffective.
- There are only limited comparative data available for lidocaine plasters, so the comparative clinical effectiveness remains unclear.
- The Preferred List options on the GGC *Formulary* for the treatment of neuropathic pain remain: amitriptyline, carbamazepine and gabapentin.

NHSGGC GUIDELINES

Primary care chronic obstructive pulmonary disease (COPD)

This guideline was developed by the Respiratory Planning Group which is a multi-disciplinary group spanning primary and acute care. The guideline was approved by the ADTC at the August meeting and can be viewed on our website. Some of the main points are shown below.

Diagnostic criteria include the existence of a persistent cough, sputum and/or breathlessness. It is important to distinguish COPD from asthma. Asthma should be considered as a possible diagnosis, particularly if the pattern of symptoms is suggestive, eg wheeze, nocturnal wakening, where the patient is a non-smoker, or the response to bronchodilator or steroid is more than 15% in FEV_1. It is important to note that the two conditions can co-exist.

Patients diagnosed with COPD are classified as follows dependent on FEV_1 results:

Mild COPD: **50 – 80% of predicted FEV_1**
Moderate COPD: **30 – 49% of predicted FEV_1**
Severe COPD: **<30% of predicted FEV_1**

These criteria have been amended from those used in previous versions of the guideline to ensure consistency with the NICE 2006 and GOLD 2007 guidelines.

Drug therapy for COPD

Pharmacological treatment initially focuses on treatment of symptoms with use of a short-acting B_2 agonist. This is chosen as the first step treatment due to the fast onset of action and low cost. If patients are still symptomatic, the next step is to add a long-acting anticholinergic followed by a long-acting B_2 agonist.

It is vital to ensure adequate inhaler technique and *Formulary* metered dose inhalers should be tried first line in Step 1. Patients should only be started on nebulised treatments when agreed with the consultant.

If the patient has suffered two or more exacerbations per year and FEV_1 <50% (may need repeat spirometry), they should be given a combination of a long-acting B_2 agonist and inhaled corticosteroid. Mucolytics should be considered in chronic productive cough.

Treatment of exacerbations

The first step is to increase the currently prescribed short-acting B_2 agonist. The recommended dose of prednisolone to treat an exacerbation is now 30mg daily for 7-14 days. This links with the NICE guidance. Antibiotics should be prescribed only if purulent sputum is present. The choices are amoxicillin 500mg three times daily or clarithromycin 500mg twice daily, both for 7 days.

Prevention of coronary heart disease and stroke

The NHSGGC Heart Managed Clinical Network (MCN) has been consolidating and updating guidelines on the management of different aspects of cardiovascular disease. The antiplatelet guidelines were highlighted in *PostScript* 45 and can be accessed on our website. Several other guidelines are in final development and will be placed on our website once approved by ADTC. These include:

- **Investigation and management of heart failure**
- **Management of persistent atrial fibrillation**
- **Diagnosis and management of hypertension.**

The MCN anticipates that the guideline on prevention of coronary heart disease and stroke will be circulated shortly and placed on our website. This updates the previous advice and takes account of some changes in evidence and national guidelines.

Lipid lowering drug therapy

In line with the NHSGGC *Formulary* Preferred List, simvastatin 40mg remains the drug of choice both for primary and secondary prevention. Atorvastatin 80mg may be considered for use first line in acute coronary syndrome with elevated troponin. Rosuvastatin has been added to the Total *Formulary*, but use is restricted to patients who fail to reach cholesterol targets in accordance with these guidelines, or for those who are intolerant of other *Formulary* statins.

Where patients fail to meet cholesterol goals on simvastatin 40mg, the following steps should be followed:
1 Check whether the patient is taking the medication as prescribed and attempt to reach concordance about the goals of treatment and importance of medication.
2 Switch to atorvastatin 20mg daily and titrate up to 80mg if still not reaching cholesterol goals.
3 Consider switching patients to rosuvastatin 20mg only if these measures fail. Doses of rosuvastatin of 40mg and above should only be initiated by, or on the advice of, a specialist. Consider rosuvastatin 5-10mg in patients who are intolerant of simvastatin and atorvastatin.
4 Ezetimibe 10mg daily is restricted to initiation by specialists when cholesterol targets are not reached on the maximum tolerated and optimised statin therapy. The combination product is non-*Formulary*.

The guideline recognises that atherosclerotic arterial disease is multifactorial and no single risk factor, including cholesterol concentration, should be viewed in isolation. All other risk factors such as smoking, hypertension and diabetes should be addressed and lifestyle advice provided on alcohol, weight management and physical activity.

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Published by the Communications Sub-group
to reflect the views of the Area Drug & Therapeutics Committee
but not necessarily those of NHS Greater Glasgow and Clyde.

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© NHSGGC Area Drug & Therapeutics Committee September 2008
Design, layout and production control:
Strathcashel Publications Project Management (01505 850 344)
Printed by: Mackay & Inglis, Glasgow