THE NHSGGC FORMULARY:
Evidence-based support for prescribers

PostScRxipt
from the
NHSGGC Area Drug & Therapeutics Committee
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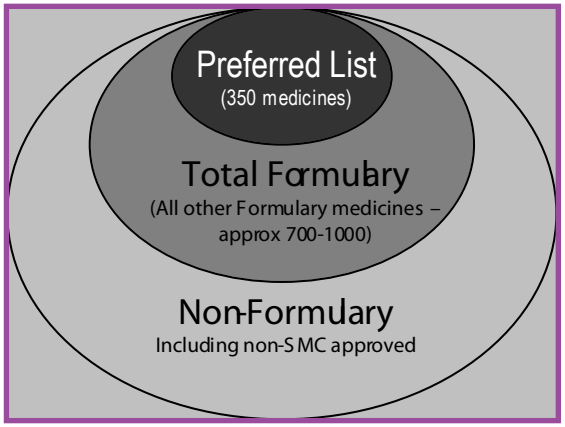
Prescribing formularies have been actively encouraged in the NHS and other healthcare systems for many years. One of the key recommendations in Audit Scotland's A Scottish prescription: Managing the use of medicines in hospitals *from 2005 is that NHS Boards should develop and monitor use of joint formularies and treatment protocols that promote cost-effective prescribing. Glasgow's* Formulary *has been in existence for 13 years. 2007 will see the first edition of the* NHS Greater Glasgow & Clyde Formulary. *The* Formulary *team explains below why it should be seen as a useful tool, shaped by prescribers for the best interests of everyone whether manager, prescriber or patient.*

What's different about the new NHSGGC *Formulary*?
Previously, the *Glasgow Formulary* consisted of a list of medicines for use within acute and primary care. A few therapeutic classes also had Drugs of Choice, which were considered to offer the maximum benefit for patients in terms of clinical effectiveness, safety, patient acceptability and cost-effectiveness.

The formation of NHSGGC offered the opportunity to review how the *Formulary* was structured. A two-tier system was chosen with medicines added to the *Formulary* falling into one of two categories: 'Preferred List' or 'Total Formulary'. The 'Preferred List' is a progression of the Drugs of Choice programme. It offers cost effective *Formulary* medicines, covering common conditions, which are appropriate for initiation in general practice and by those prescribing outwith their specialty area. The 'Total Formulary' will contain all other *Formulary* medicines, including those that are more suited to specialist initiation and use. Medicines not included in either the 'Preferred List' or the 'Total Formulary' will be considered non-*Formulary*.

The general structure of the *NHSGGC Formulary* is represented below.



The *Formulary* - a random list of drugs?
Despite being a restricted list by nature, the *Formulary* is still a useful and dynamic document. Additions to the *Formulary* are possible after a positive opinion from the SMC following their systematic review of the evidence. The ADTC bases its decisions on the detailed advice documents produced by the SMC. Local experts are consulted for their clinical opinion and practical expertise if decisions concern special patient groups. There is also a crosscheck with clinical guideline producers to ensure that local guidelines and the *Formulary* do not give conflicting information. Every effort is made to ensure *Formulary* decisions are as practice-related and clinically relevant as possible.

Ongoing inclusion of drugs in the *Formulary* is discussed during regular section reviews which involve multidisciplinary expert panels, and in some cases drugs may be removed.

The *Formulary* - restricting prescribing freedom?
Prescribers are encouraged to prescribe *Formulary* medicines and, in most cases, should consider the medicines from the 'Preferred List'. Non-*Formulary* drugs can still be prescribed, but their use is monitored to ensure this happens for valid reasons in exceptional circumstances. As part of a formulary management system, a 'Non-*Formulary* medicines target list' of high-cost and high-prescribing-volume drugs was devised. In secondary care, a non-*Formulary* form must be completed for all targeted drugs before a supply can be made to the ward. These forms can be obtained from your local pharmacy distribution or from the *Formulary* section of the intranet.

The *Formulary* - nobody listens to what prescribers want?
The ADTC is largely comprised of practising clinicians. Other prescribers can become involved and influence the content of the *Formulary* via the appeals procedure. Any consultant, GP, senior pharmacist or senior nurse who believes that an omission from the *Formulary* could compromise patient care may lodge an appeal. They are asked to provide supportive evidence in favour of the drug. The appeal is reviewed by the Formulary and New Drugs Sub-committee and the ADTC, using the evidence supplied and considering existing *Formulary* choices. The documentation can be obtained from the intranet.

A survey investigating the opinions and attitudes of GPs and consultants towards the *Formulary* and Drug of Choice scheme has just been completed. Half of all GPs and

contd on page 4

In this issue . . .

Website
http://www.glasgowformulary.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.glasgowformulary.scot.nhs.uk**

Drug	Indication under consideration (There may be other licensed indications)	Glasgow decision	
Alglucosidase alfa (Myozyme®)	Pompe disease (acid alpha-glucosidase deficiency).	Non-*Formulary*.	x
Amlodipine/valsartan (Exforge®)	Hypertension.	Non-*Formulary*.	x
Azelaic acid gel (Finacea®)	Papulopustular rosacea.	*Formulary*.	✓
Buprenorphine/ naloxone (Suboxone®)	Substitution treatment for opioid drug dependence.	*Formulary*. Restricted to those patients in whom methadone is not suitable and for whom the use of buprenorphine is considered appropriate.	✓R
Buprenorphine patches (BuTrans®)	Severe opioid responsive pain conditions which are not adequately responding to non-opioid analgesics.	Non-*Formulary*.	x
Busulfan (Busilvex®)	Conditioning treatment prior to conventional haematopoietic progenitor cell transplantation in paediatric and adult patients.	*Formulary*. Acknowledge new IV formulation.	✓
Cinacalcet (Mimpara®)	Secondary hyperparathyroidism in end stage renal disease.	Interim non-*Formulary*. Deferred to renal services for development of a treatment protocol.	?
Clofarabine (Evoltra®)	Acute lymphoblastic leukaemia in paediatric patients.	Non-*Formulary*.	x
Clostridium botulinum type A toxin (Dysport®)	Focal spasticity, including arm symptoms associated with focal spasticity, in conjunction with physiotherapy.	Non-*Formulary*.	x
Desmopressin oral lyophilisate (DDAVP Melt®)	Vasopressin-sensitive cranial diabetes insipidus and in the treatment of post-hypophysectomy polyuria/polydipsia.	*Formulary*. Acknowledge new formulation.	✓
Desmopressin oral lyophilisate (DesmoMelt®)	Primary nocturnal enuresis.	*Formulary*. Acknowledge new strength.	✓
Dexrazoxane (Savene®)	Anthracycline extravasation.	Non-*Formulary*.	x
Donepezil orodispersible (Aricept Evess®)	Mild to moderate Alzheimer's disease.	*Formulary*. Acknowledge new formulation. Restricted to patients with swallowing difficulties.	✓R
Gemcitabine (Gemzar®)	Metastatic breast cancer.	Non-*Formulary* for this indication.	x
Glyceryl trinitrate ointment (Rectogesic®)	Relief of pain associated with chronic anal fissure.	Non-*Formulary*.	x
Infliximab (Remicade®)	Moderately to severely active ulcerative colitis.	Non-*Formulary* for this indication.	x
Infliximab (Remicade®)	Severe plaque psoriasis in adults.	*Formulary*. Acknowledge new indication. Restricted to specialist use in patients who failed to respond to, or who have a contra-indication to, or are intolerant of other systemic therapy including ciclosporin, methotrexate or psoralen ultraviolet A (PUVA). To be used in accordance with the local protocol.	✓R
Ivabradine (Procoralan®)	Chronic stable angina pectoris. Restricted by the SMC to patients with a contra-indication or intolerance to beta blockers and rate-limiting calcium channel blockers.	Non-*Formulary*.	x
Lanthanum carbonate (Fosrenol®)	Phosphate-binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous peritoneal dialysis.	*Formulary*. Restricted to use as a second-line agent in patients where a non-aluminium, non-calcium phosphate binder is required on the recommendation of a consultant nephrologist.	✓R
Lidocaine plaster (Versatis®)	Post-herpetic neuralgia.	Non-*Formulary*.	x
Parathyroid hormone (Preotact®)	Severe osteoporosis in women with at least two prior vertebral fractures or equivalent high risk.	Interim non-*Formulary*. Deferred for consultation with the Osteoporosis Group	?
Pegaptanib (Macugen®)	Neovascular (wet) age-related macular degeneration.	*Formulary*. Restricted to use in patients with visual acuity between 6/12 to 6/60 (inclusive). It should be stopped if visual acuity falls below 6/60 during treatment or where severe visual loss is experienced.	✓R
Pioglitazone (Actos®)	Triple therapy in combination with metformin and a sulphonylurea in type 2 diabetes.	*Formulary*. Acknowledge new indication. Restricted to initiation and monitoring only by physicians experienced in the treatment of diabetes mellitus who can identify and manage patients who might benefit.	✓R
Rituximab (MabThera®)	Relapsed/refractory follicular lymphoma responding to chemotherapy induction that may/ may not include rituximab.	*Formulary*. Acknowledge new indication. Restricted for use only by oncologists or haematologists who have expertise in treating lymphoma in line with regional protocol.	✓R
Sitaxentan (Thelin®)	Pulmonary arterial hypertension classified as WHO functional class III, to improve exercise capacity.	*Formulary*. Restricted to specialist centres and prescribing by clinicians experienced in the management of pulmonary arterial hypertension.	✓R

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

The changing face of the Area Drug & Therapeutics Committee (ADTC)

The ADTC leads the medicines agenda on behalf of the NHS Board. Its work covers strategic, operational, professional and clinical aspects of medicines management. It aims to promote good quality and cost-effective prescribing in balance with other healthcare interventions.

Professor Martin Brodie has chaired the ADTC for the last twelve years - without missing a single meeting! After this considerable period, he has decided to step down. His tenure has seen many changes including the development of the Scottish Medicines Consortium whose first chairman, Professor David Lawson, was his predecessor as chair of Glasgow's ADTC. Professor Brodie is Clinical and Research Director of the Epilepsy Unit at the Western Infirmary. His research interests include antiepileptic neuropharmacology, the management of epilepsy, and factors affecting response to treatment. He is internationally recognised for his work and has been appointed 'Ambassador for Epilepsy' on behalf of the International League against Epilepsy and the International Bureau for Epilepsy.

The new chairman of NHS Greater Glasgow & Clyde's ADTC is Dr Jonathan Fox, Consultant Renal Physician. His main research interests are glomerulonephritis, renal function testing and initiation of dialysis. He was President of the 2006 Congress of the European Renal Association which attracted almost 6,000 delegates to Glasgow. Dr Fox has been involved with DTC structures for many years, being chair of the North Glasgow Medicines Management Committee from 2002 to 2006 and chair of Stobhill's DTC before that. He also chaired the North Glasgow Antimicrobial Group which has influenced the establishment of the Board's Antimicrobial Management Team. He has recently been appointed to the Scottish Medicines Consortium, having been a member of their New Drugs Committee since 2005.

Rimonabant

Rimonabant (Acomplia®) has not been added to the *Formulary* for the treatment of obesity. The SMC did not recommend its use in NHS Scotland. Rimonabant was associated with a reduction in mean weight of about 4-5kg over that with placebo. However, this weight was generally regained within one year of stopping treatment and the economic case was not demonstrated.

Rimonabant is an oral selective cannabinoid CB1 receptor antagonist; the first of a new class of medicines. It inhibits the effects of cannabinoid agonists within the brain and peripheral tissues which affects energy balance, glucose and lipid metabolism and modulates the intake of highly palatable, sweet or fatty foods. It is licensed as an adjunct to diet and exercise for the treatment of obese patients (BMI ≥ 30 kg/m^2), or overweight patients (BMI ≥ 27 kg/m^2) with associated risk factors, such as type 2 diabetes and dyslipidaemia.

Trials have compared rimonabant with placebo for up to two years in overweight or obese people also taking a diet reduced by 600Kcal/day. At one year, patients taking rimonabant 20mg daily showed a statistically significant weight loss compared with placebo (6.6kg vs1.8kg, p<0.001). Rimonabant achieved significantly greater reductions in waist circumference than placebo. Improvements were seen in some cardio-metabolic risk factors including HDL-C, triglycerides, and, in patients with type 2 diabetes, HbA1c.

A reduction of at least 10% in weight from baseline is considered clinically significant; only up to a third of patients on rimonabant achieve this (16-33% compared to 2-8% with placebo) with the lost weight generally being regained within one year of stopping treatment. The clinical significance of these short-term effects on long-term outcomes is unknown. There are no trials comparing rimonabant with orlistat and sibutramine, the other drugs licensed for treatment of obesity.

The most common adverse effects include nausea, diarrhoea, vomiting, anxiety, insomnia, mood disorder, depressive symptoms and sleep disorders.

Summary

• Rimonabant has not been added to the *Formulary* and has not been recommended by the SMC.

• Rimonabant was associated with a reduction in mean weight of about 4-5kg over that with placebo. However, this weight was generally regained within one year of stopping treatment.

• Practitioners in areas with access to the Glasgow Weight Management Service should refer patients with BMI ≥ 30 plus co-morbidities or BMI ≥ 35 without co-morbidities.

The NHSGGC Formulary *contd from page 1*

consultants were randomly selected to receive the survey. Findings from this survey (which had an excellent 51% response rate) will help develop the *Formulary* and will be highlighted in a future *PostScript*.

The *Formulary* - never up to date anyway?

The 'Preferred List' *Formulary* will be published in paper format every August. Formulary updates are published every two months in *PostScript*. In primary care, a version of the *Formulary* for GPASS, Scotland's most commonly used GP prescribing software system, has been used in many practices and will soon be re-launched.

The *Formulary* - why bother?

The *Formulary* is a list of drugs which aims to meet the therapeutic needs of the majority of patients and to reflect current prescribing in secondary and primary care. To ensure that we produce a practice-driven, useful and accepted document, it is important that there is continued feedback from users. This way we can produce a *Formulary* that is a quality tool for up-to-date prescribing guidance.

New *PostScript* bulletins

Two new bulletins have been added to the *PostScript* family.

• ***PostScript Oncology*** is a re-badging of *Oncology Pharmacy Update*, a two-monthly newsletter on local and national decisions which may affect the use of medicines in oncology. It is distributed by Jennifer Laskey, Clinical Effectiveness Pharmacist for Oncology.

• The first edition of ***PostScript Safety*** has recently been published by the Safer Use of Medicines Sub-committee of the ADTC and can be accessed on our website. It provides information to prevent or reduce the frequency and severity of harm arising from the use and misuse of medicines. This will include monitoring reported incidents and giving advice on risk management strategies addressing practical prescribing, dispensing and administration issues.

NHS Greater Glasgow and Clyde

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The NHSGG&C Formulary – evidence based support for prescribers
A Scottish prescription: Managing the use of medicines in hospitals http://www.accounts-commission.gov.uk/publications/pubs2005.htm

Rimonabant
http://www.scottishmedicines.org.uk/smc/files/rimonabant%20_Acomplia_%20%20_341-07_.pdf