PostScRipt

from the
NHSGGC Area Drug & Therapeutics Committee
Issue 41 September 2007

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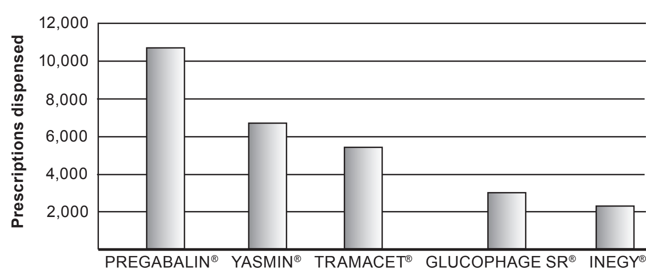
Website
http://www.ggcformulary.scot.nhs.uk

THE SMC AND THE NHSGGC FORMULARY

Advice from the SMC directs many of the decisions about *Formulary* inclusion for new drugs. Drugs that have not been accepted for use by SMC automatically become non-*Formulary*. Procedures are in place in both primary and secondary care for monitoring of SMC non-approved drugs and high profile non-*Formulary* drugs. Some of the current high profile items are listed below along with suggestions for *Formulary* alternatives. If just half of the usage of these SMC non-approved products had been switched to the suggested *Formulary* alternatives, savings of around £400,000 could have been made in the last year.

Please note the following are also 'not recommended' by SMC and should only be prescribed, or recommended for prescribing, under exceptional circumstances; buprenorphine (BuTrans®, Transtec®) patches, diclofenac (Voltarol® Gel) patches, estradiol and drosperinone (Angeliq®), macrogol 4000 (Idrolax®), memantine (Ebixa®), nicotinic acid MR (Niaspan®) and rimonabant (Acomplia®).

Prescribing of non-SMC approved drugs NHSGGC April 2006-March 2007



Thinking of prescribing this non-*Formulary* drug?	Why not try one of the *Formulary* options?
Pregabalin (Lyrica®) for neuropathic pain, SMC 'not recommended': comparative clinical and cost effectiveness were not demonstrated. SMC stated that further controlled data are needed to establish its place in therapy in patients refractory to, or intolerant of, other pharmacological treatments. It is acknowledged that some use is for epilepsy (accepted by SMC). £ Additional £610/patient/year on average against generic gabapentin.	Amitriptyline (unlicensed) Carbamazepine Gabapentin
Drospirenone plus ethinyloestradiol (Yasmin®) for contraception, SMC 'not recommended': substantially more expensive than competitor products and provides little additional benefit for this extra cost. £ Additional £46/patient/year against an average of *Formulary* choices.	Cilest® Loestrin 30® Microgynon®
Tramadol plus paracetamol (Tramacet®) for moderate to severe pain, SMC 'not recommended': appears to have similar efficacy to some other combination analgesics, but at higher cost. Also significantly more expensive than its individual components prescribed separately. Tramadol is non-*Formulary*. £ Additional £239/patient/year on average against components (not equivalent strengths). Additional £248/patient/year on average against co-codamol 30/500.	Co-codamol 30/500 Dihydrocodeine + paracetamol
Metformin (Glucophage SR®) for type-2 diabetes, SMC 'not recommended': evidence of improved gastrointestinal tolerability is not convincing and it is more expensive than the immediate-release formulation. £ Additional £61/patient/year on average against standard release tablets.	Metformin standard release
Ezetimibe / simvastatin (Inegy®) for lipid lowering, SMC accepted for restricted use: for patients who have failed to achieve target cholesterol levels after optimisation of statin therapy and where these two drugs were appropriate. However, this decision was at a time when the cost of Inegy® was similar to the individual components; this is no longer the case due to Drug Tariff price changes. Inegy is non-*Formulary* as the local guideline group did not see a place for this treatment. The preferred treatment pathway in NHSGGC after failure of simvastatin 40mg is to move to atorvastatin, a more potent option, and increase the dose appropriately. If cholesterol levels are still high at the maximum licensed or tolerated dose, ezetimibe may be added. £ Additional £121/patient/year against components. Additional £140/patient/year against atorvastatin 40mg.	Atorvastatin Atorvastatin + ezetimibe

For all article references, check our website
http://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)	Glasgow decision	
Bemiparin (Zibor®)	Established deep vein thrombosis, with or without pulmonary embolism, during the acute phase.	Non-*Formulary.*	x
Bemiparin (Zibor®)	Prevention of thromboembolic disease in patients undergoing orthopaedic surgery.	Non-*Formulary.*	x
Bevacizumab (Avastin®)	First-line treatment of patients with metastatic breast cancer.	Non-*Formulary.*	x
Bortezomib (Velcade®)	Monotherapy for progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone, or are unsuitable for, bone marrow transplantation.	Non-*Formulary* for this indication.	x
Clopidogrel (Plavix®)	ST segment elevation acute myocardial infarction, in combination with aspirin, in medically treated patients eligible for thrombolytic therapy.	*Formulary* (Preferred List). Acknowledge new indication. Restricted for specialist initiation in combination with aspirin post ST segment elevation acute myocardial infarction (STEMI) with continuation for 4 weeks.	√R
Erlotinib (Tarceva®)	Metastatic pancreatic cancer in combination with gemcitabine.	Non-*Formulary* for this indication.	x
Exenatide (Byetta®)	Type 2 diabetes mellitus in combination with metformin and/or sulphonylureas.	*Formulary* (Total Formulary). Restricted to specialist initiation as an alternative to insulin in patients who have failed treatment on metformin and/or sulphonylureas and in whom insulin would be the next treatment option.	√R
Ibritumomab tiuxetan (Zevalin®)	Treatment of adult patients with rituximab relapsed or refractory CD20+ follicular B-cell non-Hodgkin's lymphoma following the incorporation of Yttrium 90.	Non-*Formulary.*	x
Idursulfase (Elaprase®)	Long-term treatment of patients with Hunter syndrome (Mucopolysaccharidosis II, MPS II).	Non-*Formulary.*	x
Imiquimod (Aldara®)	Topical treatment of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses on the face or scalp in immunocompetent adult patients when size or number of lesions limit the efficacy and/or acceptability of cryotherapy and other topical treatment options are contraindicated or less appropriate.	Non-*Formulary* for this indication.	x
Insulin detemir	Diabetes mellitus (in patients for whom insulin detemir is an appropriate choice of insulin and who have poor visual acuity and dexterity problems).	*Formulary* (Total Formulary). Acknowledge new formulation. Restricted to initiation by consultant diabetologists in patients with severe/ frequent nocturnal hypoglycaemia. Not for routine use in type 2 diabetes unless patients suffers from recurrent episodes of hypoglycaemia.	√R
Liposomal cytarabine (DepoCyte®)	Intrathecal treatment of lymphomatous meningitis.	Non-*Formulary.*	x
Methylphenidate (Medikinet XL®)	Attention Deficit Hyperactivity Order (ADHD) in children over six years of age.	*Formulary* (Total Formulary). Acknowledge new formulation. Restricted to initiation by a specialist in childhood behaviour disorders. Second line to standard release tablets and used for patients requiring methylphenidate in the morning and afternoon when administration of midday dose is problematic or inappropriate.	√R
Montelukast (Singulair Paediatric®)	An alternative to low-dose inhaled corticosteroids for children aged 2 to 14 years with mild persistent asthma who do not have a recent history of serious asthma attacks that required oral corticosteroid use, and who have demonstrated that they are not capable of using inhaled corticosteroids.	*Formulary* (Preferred List). Acknowledge new indication. Restricted to initiation by specialists in paediatric asthma care.	√R
Nebivolol (Nebilet®)	Stable mild and moderate chronic heart failure in addition to standard therapies in elderly patients >70 years.	Non-*Formulary.*	x
Pregabalin (Lyrica®)	Central neuropathic pain in adults.	Non-*Formulary* for this indication.	x
Rotigotine (Neupro®)	Signs and symptoms of early-stage idiopathic Parkinson's disease as monotherapy.	*Formulary (Total Formulary). Restricted to specialist initiation for patient where the transdermal route would facilitate treatment.*	√R
Rotigotine (Neupro®)	Signs and symptoms of advanced idiopathic Parkinson's disease in combination with levodopa, ie over the course of the disease, through to late stages when the effect of levodopa wears off or becomes inconsistent and fluctuations of the therapeutic effect occur (end of dose or 'on-off' fluctuations).	*Formulary* (Total Formulary). Restricted to specialist initiation for patients where the transdermal route would facilitate treatment.	√R
Sunitinib (Sutent®)	Advanced and/or metastatic renal cell carcinoma.	Non-*Formulary.*	x
Trastuzumab (Herceptin®)	Metastatic breast cancer in combination with an aromatase inhibitor.	Non-*Formulary* for this indication.	x
Triptorelin (Decapeptyl® SR)	Endometriosis (ADTC appeal).	*Formulary* (Total Formulary).	√R

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

Lidocaine 5% plaster (Versatis®)

Lidocaine plaster is licensed for the treatment of neuropathic pain associated with previous herpes zoster infection (post-herpetic neuralgia, PHN). It was rejected for inclusion in the *Formulary* in April 2007 following SMC advising it was not recommended for use. The main reasons for the SMC decision were:

- Lack of long-term data on the benefits of lidocaine plaster over placebo. The studies available mainly examine effects of application of ≤ 12hours within a 24-hour period over a period of 14-21 days. PHN can last for several years.
- There are no available data for direct comparison with other licensed PHN treatment alternatives, therefore the relative efficacy and safety of lidocaine plaster is not known.
- Indirect comparison data with gabapentin (1800mg) do not produce any robust evidence that lidocaine plaster is likely to produce more clinical benefit than gabapentin.
- The physical barrier created by the plaster over the sensitive area seems to contribute to an analgesic effect. This might explain why, in a parallel group study, lidocaine plaster has shown non-significant differences compared to placebo for pain-reduction and pain relief.
- Lidocaine plaster costs are £880-£2650 per year compared to £17-£408 for *Formulary* alternatives.

Non-*Formulary* prescribing policy

The Prescribing Management Group has recently approved a non-*Formulary* (NF) prescribing policy for employed staff in all directly provided NHSGGC services. A complementary policy will apply to prescribing by independent contractors in primary care. The policy will apply to all patients, whether NHSGGC residents or referred for treatment from a neighbouring NHS Board. The intention is to ensure a fair and consistent approach across NHSGGC.

NHSGGC has a robust and well-established *Formulary* management system. An evidence-based review process is conducted at national and local level to influence prescribing recommendations. Medicines successfully passing through this process are included in the 'Preferred List' or 'Total Formulary'. These are intended to cover the vast majority of patient requirements, providing clinicians with a wide range of cost-effective prescribing options. Where circumstances dictate that a medicine should only be prescribed on a limited basis, the *Formulary* will specify these restrictions.

Policy statement

Prescribing from the *Formulary* is consistent with good clinical practice. The need for NF prescribing is recognised, but it is expected that:

- formal treatment guidelines/protocols will exclude NF drugs;
- NF status will apply to new medicines until accepted by the SMC and the ADTC;
- NF prescribing will be necessary and approved only in exceptional circumstances where such NF prescribing is in the best interests of an individual patient.

Monitoring and review

- Each directorate or partnership will have a clear process to review NF requests and will be responsible for ensuring its implementation and monitoring. Requests will only be approved where there is a clear and overriding clinical case that *Formulary* prescribing is not possible.
- Each directorate should develop systems to monitor and review NF prescribing, which will engage with the individual prescriber and will identify any emerging patterns of use at service or directorate level.
- Such processes are under development. More information will be provided in due course within directorates and partnerships.

Webwatch:
Keeping up to date with medical news

NeLM (National Electronic Library for Medicines)

NeLM (formerly Druginfozone) is a medicines information knowledge base for NHS health professionals. The independent, evidence based content aims to promote safe and effective use of medicines. This is a free service; anyone working in the NHS can register. There is a wide range of useful information including current awareness, drug reviews and drug alerts. It is updated daily.

One particularly useful service is NeLM News. This provides daily important and relevant news about medicines and related practice. It is written by medicines information pharmacists who scan a variety of peer-reviewed journals, reputable international health news websites, UK government websites and other UK health related organisations. News items are reviewed and, in some cases, critically evaluated. Relevant articles are reported as soon as possible after they are published.

The type of material includes:

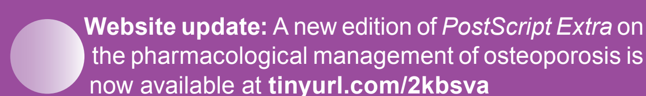
- MHRA safety reports or alerts
- SMC/NICE advice
- Major trials, systematic reviews or health economic studies covering drugs or lifestyle interventions which involve medicines or pharmacy
- Studies given coverage by the BBC or national newspapers
- UK product launch information or significant product licence changes.

Registering for this service on the website (**www.nelm.nhs.uk**) allows you to receive daily updates. The news items often link to the original article and are a great way of keeping up to date without scanning a large number of journals. Contact your local MI Centre for further advice:

- Glasgow Royal Infirmary 0141 211 4407
- Inverclyde Royal Hospital 01475 504305
- Royal Alexandra Hospital 0141 314 6819
- Southern General Hospital 0141 201 1381
- Vale of Leven Hospital 01389 754121
- Yorkhill 0141 201 0626

Hitting the Headlines

Hitting the Headlines (**www.library.nhs.uk/rss/**) is a service from the National Library for Health. It aims to ensure that patients and health professionals are better informed about the accuracy of reporting of research into the effectiveness of new treatments, drugs and other health care interventions in the press. It assesses the reliability of both the journalists' reporting of health stories and the research on which they are based. It provides a rapid assessment of the original research behind the news story and evaluates how accurately the journalists have reported the findings of the research. Summaries of news stories are produced within 48 hours of their publication.



Website update: A new edition of *PostScript Extra* on the pharmacological management of osteoporosis is now available at **tinyurl.com/2kbsva**

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