NOVO NORDISK INSULIN WITHDRAWALS

In May 2005, Novo Nordisk announced the withdrawal of the following insulins:

- **Human Actrapid (not 10ml vials)**
- **Human Mixtard (10, 20, 30, 40, 50) Novolet pens**
- **Human Insulatard Novolet and Flexpen devices**
- **Monotard and Ultratard 10ml vials**

The GGHB Diabetes Managed Clinical Network (MCN) recognised the potential impact on care for a large number of patients and set up a structured process to manage this.

Eli Lilly and Sanofi-Aventis continue to manufacture insulins comparable to those being withdrawn. While some patients might benefit from switching to a short-acting analogue, the MCN recommends that patients are switched to the appropriate direct comparator (human) insulin. Switching to analogues requires extra advice and support from Diabetes Specialist Nurses (DSNs) and should only be carried out in conjunction with a consultant diabetologist.

The following process is currently underway:

- All adult hospital diabetes centres are identifying affected patients opportunistically and carrying out switches.
- Yorkhill's diabetes service will be responsible for the changes required for all of their patients.
- DSNs are working with GP practices to obtain lists of affected patients. DSN contact details are listed in *PostScript Primary Care*, July 2005.
- All patients will receive a letter explaining why changes are necessary and how they are likely to be affected.
- Patients will also be given information when they are collecting prescriptions at community pharmacies.
- Patients will be asked to contact a named person in their locality who will arrange appointments for each patient to have their prescription changed.
- Patients will generally be given the option of whether this will happen through their hospital diabetes centre (if they are attending one) or their local DSN.
- Each LHCC has agreed to provide administrative and clerical support.
- The withdrawal is to take place by December 2005 so this work needs to progress quickly. The MCN is grateful for the cooperation already received from clinicians.
- The MCN is disappointed at the action of Novo Nordisk in pursuing this withdrawal programme but recognises that it is a commercial decision.
- The process is being continually monitored by the MCN.

Correction: In the *Formulary News* article on triptorelin in *PostScript* 28 (July 2005), the "practical issues" entry in the table relating to a relatively large needle should refer to goserelin, not triptorelin. The web version has been updated.

For all article references, please check our website.

PostScRipt
from the
GGNHSB Area Drug & Therapeutics Committee
Issue 29 September 2005

In this issue . . .

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

Updates to lipid lowering therapy advice

Atorvastatin 80mg daily may be initiated by consultants in patients with definite coronary artery disease who present with acute coronary syndrome (acute MI or unstable angina) confirmed by elevated troponin concentration. This follows the PROVE-IT study where atorvastatin 80mg daily gave a significant reduction (from 26.3% to 22.4%; 2-year NNT=26) in the primary end-point of death from any cause, MI, unstable angina requiring hospitalisation, revascularisation and stroke compared to pravastatin 40mg.[1]

Atorvastatin may also be initiated in patients who fail to meet cholesterol goals on the drug of choice, simvastatin 40mg. Patients should be switched to atorvastatin with up-titration if required to 80mg rather than increasing the dose of simvastatin.

Inegy® (MSD/Schering-Plough) has not been added to the *Formulary*. It is a combination of ezetimibe 10mg with simvastatin 20, 40 or 80mg. Both drugs are on the *Formulary* but some strengths of the combination are more expensive than the components given separately. Ezetimibe is restricted to initiation by specialists when cholesterol targets are not reached on the maximum tolerated and optimised statin therapy.

The *Formulary* and cholesterol guidelines have been updated to take account of these changes.

More information on this issue is available on the website. This is the last *PostScript* to include ADTC decisions from two meetings and so has an unusually large SMC table. Future two-monthly editions will have more detailed articles on prescribing issues.

Updated *Glasgow Formulary*

The twelfth edition of the *Glasgow Formulary* has just been published and will be available on our website **www.glasgowformulary.scot.nhs.uk** Since last time, there have been revisions of the ACE inhibitor and angiotensin-II receptor antagonist sections and the antidepressant guidelines. Prescribing notes have been reviewed throughout. Work is underway on two electronic versions of the *Formulary*. One will be incorporated into the Digital BNF which will be available on the pan NHS Glasgow intranet, the other is being developed for the primary care GPASS system.

Incremental alphabetical list of published SMC advice on which Glasgow decisions have recently been taken.
For further information and a full list of SMC advice, visit **www.scottishmedicines.org**

Drug	Reason for Consideration	Indication / Pharmacology	SMC decision	Glasgow decision
Abacavir (Ziagen®)	Product update	Treatment of HIV-1 infected adults and adolescents over 12 years, in combination with other antiretroviral medicinal products.	Accepted for use in a once-daily dosing schedule within NHS Scotland.	*Formulary.* Acknowledge change in licence.
Abacavir / Lamivudine (Kivexa®)	New formulation	Treatment of HIV-1 infected adults and adolescents over 12 years, in combination with other antiretroviral medicinal products.	Accepted for use within NHS Scotland.	*Formulary.* Acknowledge new formulation.
Anastrozole (Arimidex®)	New indication	For adjuvant treatment of postmenopausal women with hormone receptor-positive early invasive breast cancer.	Accepted for restricted use within NHS Scotland. Restricted to initiation by oncologists.	*Formulary.* Acknowledge new indication. SMC restrictions apply.
Aripiprazole (Abilify®)	New formulation	Treatment of schizophrenia.	Accepted for restricted use within NHS Scotland. Where aripiprazole is an appropriate antipsychotic, this new dosage is restricted to patients who may benefit from a dose reduction to 5mg daily, taking account of SMC advice issued in August 2004.	*Formulary.* Acknowledge new formulation. Restricted to initiation by consultant psychiatrist; SMC restrictions apply.
Aprepitant (Emend®)	New medicine	Prevention of acute and delayed nausea and vomiting associated with highly emetogenic cisplatin-based chemotherapy	Accepted for restricted use within NHS Scotland. It should be initiated only by appropriate hospital-based specialists.	Non-*Formulary.*
Atomoxetine (Strattera®)	New medicine (Resubmission)	Treatment of ADHD in children of 6 years and older and in adolescents as part of a comprehensive treatment programme.	Accepted for restricted use within NHS Scotland. Restricted to use in patients who do not respond to stimulants or in whom stimulants are contraindicated or not tolerated. Restricted to use by physicians with appropriate knowledge and expertise in treating ADHD.	*Formulary.* SMC restrictions apply.
Brimonidine tartrate / timolol eye drops (Combiglan®)	New formulation	Reduction of intra-ocular pressure in patients with chronic open-angle glaucoma or ocular hypertension who are insufficiently responsive to topical beta-blockers alone and for whom brimonidine is an appropriate adjuvant therapy.	Accepted for use within NHS Scotland.	*Formulary.*
Capecitabine (Xeloda®)	New indication	For adjuvant treatment following surgery for Stage III (Dukes' C stage) colon cancer.	Accepted for use within NHS Scotland.	*Formulary.* Acknowledge new indication.
Carbomer (Liquivisc®)	New medicine	Symptomatic treatment of dry eye syndrome where a carbomer product is the treatment of choice.	Accepted for use within NHS Scotland.	Decision deferred for consultation with ophthalmologists.
Ciclesonide (Alvesco®)	New medicine	Prophylactic treatment of persistent asthma in adults (18 years and older).	Accepted for use within NHS Scotland.	Decision deferred for *Formulary* section review.
Cinacalcet (Mimpara®)	New medicine	Treatment of secondary hyperparathyroidism in patients with end-stage renal disease on maintenance dialysis therapy.	Not recommended for use within NHS Scotland.	Non-*Formulary.*
Cytarabine (DepoCyte®)	New formulation	Intrathecal treatment of lymphomatous meningitis.	Not recommended for use within NHS Scotland.	Non-*Formulary.*
Duloxetine (Cymbalta®)	New indication	Treatment of major depressive episodes.	Accepted for restricted use within NHS Scotland. Restricted to patients who have not responded to or are unable to tolerate initial treatment options.	*Formulary.* Acknowledge new indication. Restricted to psychiatrist initiation as third line treatment for major depressive episodes.
Eflornithine (Vaniqa®)	New medicine (Resubmission)	Treatment of facial hirsutism in women.	Accepted for restricted use within NHS Scotland. Restricted to use in women for whom alternative drug therapy is ineffective, contra-indicated or considered inappropriate.	*Formulary.* SMC restrictions apply.
Eplerenone (Inspra®)	New medicine (Resubmission)	Addition to standard therapy including beta-blockers, to reduce the risk of cardiovascular mortality and morbidity 3 - 14 days after myocardial infarction in stable patients with left ventricular dysfunction (LVEF ≤ 40%) and clinical evidence of heart failure.	Accepted for use within NHS Scotland.	*Formulary.* To be initiated only in patients: a) with left ventricular systolic dysfunction accompanied by evidence of heart failure, both manifest within 3-14 days of myocardial infarction. Consultant signature required. b) already on spironolactone who have intolerable sex hormone mediated adverse effects.
Ezetimibe / Simvastatin (Inegy®)	New formulation	Treatment of primary hypercholesterolaemia, mixed hyperlipidaemia or homozygous familial hypercholesterolaemia.	Accepted for restricted use within NHS Scotland.	Non-*Formulary.*
Fentanyl patch (Durogesic Dtrans®)	New formulation	Chronic intractable pain due to non-malignant conditions.	Accepted for restricted use within NHS Scotland. Restricted for patients whose pain is stable and has initially been controlled by oral means. Use should focus on patients with difficulty swallowing or have opiate-induced constipation.	*Formulary*. Acknowledge new formulation. SMC restrictions apply.
Fosamprenavir (Telzir®)	New medicine	Treatment of HIV-1 infected adults in combination with other antiretroviral medicinal products.	Accepted for use within NHS Scotland.	Non-*Formulary*.
Galantamine (Reminyl XL®)	New formulation	Treatment of mild to moderately severe dementia in Alzheimer's disease in patients for whom therapy with galantamine is appropriate.	Accepted for use within NHS Scotland.	*Formulary*. Acknowledge new formulation.
Ibritumomab Tiuxetan (Zevalin®)	New medicine	Treatment of adult patients with rituximab relapsed or refractory CD20+ follicular B-cell non-Hodgkin's lymphoma following the incorporation of Yttrium 90.	Not recommended for use within NHS Scotland.	Non-*Formulary*.
Imiquimod (Aldara®)	New medicine	Topical treatment of small superficial Basal Cell Carcinoma (sBCC) in adult patients.	Accepted for restricted use within NHS Scotland for adults in whom standard treatment with surgery or cryotherapy is contraindicated. Use should be supervised by dermatology specialists.	*Formulary*. SMC restrictions apply.
Insulin detemir (Levemir®)	New indication	Treatment of diabetes mellitus in children and adolescents.	Accepted for restricted use within NHS Scotland. Restricted to patients attempting to achieve better glycaemic control.	*Formulary*. SMC restrictions apply.
Letrozole (Femara®)	New indication	Treatment of invasive early breast cancer	Accepted for use within NHS Scotland for the treatment of invasive early breast cancer in postmenopausal women who have already received standard tamoxifen therapy. Treatment should continue for three years or until the tumour gets worse, whichever occurs first.	*Formulary*. Restricted to initiation by specialists. SMC restrictions apply.
Modafinil (Provigil®)	Resubmission	Treatment of excessive sleepiness associated with obstructive sleep apnoea/ hypopnoea syndrome.	Not recommended for use within NHS Scotland.	Non-*Formulary*.
Modafinil (Provigil®)	New indication	Treatment of excessive sleepiness associated with moderate to severe chronic shift work sleep disorder.	Not recommended for use within NHS Scotland.	Non-*Formulary*.
Montelukast (Singulair®)	New Indication	In those asthmatic adults in whom montelukast is indicated in asthma, montelukast can also provide symptomatic relief of seasonal allergic rhinitis.	Accepted for restricted use within NHS Scotland. Restricted to the relief of seasonal allergic rhinitis symptoms in adult patients who require montelukast for their asthma.	Non-*Formulary* for this indication.
Oxybutynin (Kentera®)	New formulation	Symptomatic treatment of urge incontinence and / or increased urinary frequency and urgency as may occur in patients with unstable bladder.	Accepted for restricted use within NHS Scotland. Restricted to patients who benefit when taking oxybutynin by mouth but experience intolerable side effects.	*Formulary*. Acknowledge new formulation. SMC restrictions apply.
Oxycodone (OxyContin®)	New indication	Treatment of severe pain requiring the use of a strong opioid.	Accepted for restricted use within NHS Scotland.	*Formulary*. Acknowledge new indication. Restricted to use in patients in whom controlled release morphine sulphate is ineffective or not tolerated.
Paracetamol infusion (Perfalgan®)	Product update	Treatment of moderate pain following surgery, and short-term treatment of fever.	Accepted for use within NHS Scotland for use in children weighing less than 33 kg but more than 10kg for the short-term treatment of moderate pain following surgery, and short-term treatment of fever, when administration by the intravenous route is clinically justified.	*Formulary*. Acknowledge new indication.

Medicine	Reason for consideration	Indication	SMC decision	Glasgow decision
Pegylated interferon alfa 2a (Pegasys®)	New indication	Treatment of chronic hepatitis B in adult patients with compensated liver disease and evidence of viral replication, increased ALT and histologically verified liver inflammation and / or fibrosis.	Accepted for use within NHS Scotland.	*Formulary.* Approved for restricted use subject to local protocol review by Hepatitis Treatment & Care Subgroup.
Pemetrexed (Alimta®)	New medicine	In combination with cisplatin for the treatment of chemotherapy-naïve patients with unresectable malignant pleural mesothelioma.	Accepted for restricted use within NHS Scotland. Restricted to the treatment of patients who have not had cancer treatment and have mesothelioma that is spreading and inoperable.	*Formulary.* Restricted to specialist use. SMC restrictions apply.
Pioglitazone (Actos®)	Resubmission	Monotherapy in type 2 diabetes mellitus patients, particularly overweight patients, inadequately controlled by diet and exercise for whom metformin is inappropriate because of contra-indications or intolerance.	Accepted for restricted use within NHS Scotland.	*Formulary.* Restricted to monotherapy in type 2 diabetes mellitus patients in whom consideration is otherwise given to insulin therapy.
Rosiglitazone Maleate (Avandia® Triple Therapy)	New indication	Triple oral therapy in combination with metformin and a sulphonylurea in patients (particularly overweight patients) who are unable to achieve sufficient glycaemic control despite dual oral therapy and where patients are unable or unwilling to take insulin.	Accepted for restricted use within NHS Scotland. Restricted to use in patients who already have experienced severe hypoglycaemia or patients in whom metformin and sulphonylureas are contraindicated or not tolerated.	*Formulary.* Restricted to initiation and monitoring only by physicians experienced in the treatment of diabetes mellitus able to identify and manage patients who might benefit. SMC restrictions apply.
Strontium ranelate (Protelos®)	New medicine	Treatment of postmenopausal osteoporosis to reduce the risk of vertebral and hip fractures.	Accepted for restricted use within NHS Scotland. Restricted to use in women ≥75 years with previous fracture and T-score <-2.4 when bisphosphonates are contra-indicated or not tolerated.	*Formulary.* SMC restrictions apply.
Tamsulosin (Flomaxtra® XL)	New formulation	Functional symptoms of benign prostatic hypertrophy.	Accepted for use within NHS Scotland.	*Formulary.* Acknowledge new formulation.
Vinorelbine (Navelbine®)	New formulation	As a single agent or in combination for the first line treatment of stage III or IV non-small-cell lung cancer.	Accepted for restricted use within NHS Scotland. Restricted to use by cancer specialists as an alternative method of administration.	Decision deferred for consultation with the Drugs in Oncology Group and Regional Prescribing Advisory Group.
Voriconazole (Vfend®)	New indication	Treatment of candidaemia in non-neutropenic patients.	Accepted for restricted use within NHS Scotland. Restricted to patients with infection resistant to fluconazole who do not benefit from or cannot tolerate treatment with amphotericin B, or who are at increased risk of serious side-effects with amphotericin.	*Formulary.* Acknowledge new indication. SMC restrictions apply.
Buprenorphine (Subutex®)	ADTC Appeal	Acute detoxification of opiate dependent patients		*Formulary.* Restricted to use by specialists within addiction services as the first line agent for acute detoxification of opiate dependent patients and for use in maintenance therapy only in exceptional circumstances. Subject to development of a protocol for use.
Vardenafil (Levitra®)	ADTC Appeal	Treatment of erectile dysfunction	Accepted for use within NHS Scotland	*Formulary*.

PostScript

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

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Design, layout and production control:
Strathcashel Publications Project Management (01505 850 344)
Printed by: Core Image, East Kilbride